

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 876, 878, and 886****[Docket No. FDA-2018-N-3066]****Medical Devices; Classification of Accessories Distinct From Other Devices; Finalized List of Accessories Suitable for Class I****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final classification action.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is classifying suitable accessories into class I as required by the FDA Reauthorization Act of 2017 (FDARA). The Agency has determined that general controls alone are sufficient to provide reasonable assurance of safety and effectiveness for these accessories. We made this determination based on the risks of the accessories when used as intended with other devices such as the parent or system.

**DATES:** This final classification action is effective May 13, 2019.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final classification action into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993-0002, 301-796-5678.

**SUPPLEMENTARY INFORMATION:****I. Background**

On August 18, 2017, FDARA was signed into law (Pub. L. 115-52). Section 707 of FDARA amended section 513(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)) and, among other amendments, created a process for FDA to propose a list of accessories suitable for distinct classification into class I. Section 513(f)(6)(D)(i) of the FD&C Act mandated that FDA make the first such proposal within a year of enactment of FDARA, and FDA published that proposal in the **Federal Register** of August 17, 2018 (83 FR 41023). Section 513(f)(6)(D)(i) also requires that FDA publish a final action classifying

suitable accessories into class I within 180 days after the end of the comment period. This final classification action fulfills that requirement.

In the proposal, we explained that the classification of each accessory is based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used (see section 513(f)(6)(A) of the FD&C Act).

In general, we considered an accessory to be eligible for classification into class I distinct from another device if the accessory: (1) Is not for use in supporting or sustaining human life, or of substantial importance in preventing impairment to human health; (2) does not represent a potential unreasonable risk of illness or injury; and (3) general controls alone would be sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Note that by regulation, design controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.30(a)(2)(ii) (21 CFR 820.30(a)(2)(ii)). Thus, if an accessory is not automated with computer software but would require design controls to provide reasonable assurance of safety and effectiveness, we did not consider it eligible for this classification process.

In this final classification action, we are classifying into class I all of the accessories that we proposed as suitable for distinct classification in class I. We are not including additional accessories in this final classification action, but FDA intends to publish another proposed list of accessories that may be suitable for distinct classification into class I in accordance with the statutory deadline of 5 years from the first such proposal (see 21 U.S.C. 360c(f)(6)(D)(i)).

**II. Comments on the Proposal**

FDA received comments from industry, trade associations, and individuals on FDA's proposal. Various comments were regarding topics that were determined to be outside the scope of this final classification action. We have considered the remaining comments and respond briefly to them as follows. The order of response to the commenters is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar. In several comments, commenters requested

"guidance" on various topics, which we have interpreted to mean additional information rather than FDA guidance within the meaning of 21 CFR 10.115(b).

(Comment 1) One commenter stated that class I devices should include a disclaimer that serious harm may result from their improper use or installation. The commenter believes this will provide an incentive for patients to ask their doctors about the proper use of devices because patients may not see device labeling.

(Response) Class I devices are subject to general controls, which are defined in section 513(h)(1) of the FD&C Act. These general controls include, but are not limited to, certain labeling requirements under the FD&C Act and part 801 (21 CFR part 801), among other provisions. Changes to labeling requirements under the FD&C Act and part 801 are outside the scope of this final classification action.

(Comment 2) Several commenters suggested that additional product codes be considered for distinct classification into class I. One of these commenters believes that many of the accessories listed in the comment were considered by FDA to have a higher classification solely due to the risk of the parent device and FDA's previous review practices. That commenter believes some of these accessories fall under existing class I classification regulations and should be placed into class I through this final classification action.

(Response) We have reviewed all product codes suggested for distinct classification into class I in response to comments and have determined that additional product codes identified are not appropriate for this list at the present time for one or more of the following reasons: (1) The accessory type is already distinctly classified; (2) the accessory is of a type that is already class I; or (3) insufficient information was provided to demonstrate that general controls alone will provide reasonable assurance of safety and effectiveness.

FDA will consider additional product codes for distinct classification into class I as part of a future proposal in accordance with the statutory deadline of 5 years from the first such proposal under section 513(f)(6)(D)(i) of the FD&C Act. If a manufacturer or importer with marketing authorization for an accessory believes its accessories are suitable for distinct classification, the manufacturer or importer can also request a class I designation through an existing accessory request pursuant to section 513(f)(6)(D)(ii) of the FD&C Act.

(Comment 3) One commenter requested clarification on two of FDA's

proposed regulations for penile implant surgical accessories and implanted mechanical/hydraulic urinary continence device surgical accessories. This includes the identification of product code FAE for penile implant surgical accessories, and specific edits to the list of accessories included in FDA's proposal.

(Response) FDA agrees with the commenter. The identified accessories intended for use with a penile prosthesis under product codes FAE and FTQ were within FDA's intent, but the proposal did not make that clear. FDA has also clarified that penile implant surgical accessories suitable for class I include the cylinder insertion needle, device placement tool, tubing plug, and blunt needle. Additionally, implanted mechanical/hydraulic urinary continence device surgical accessories suitable for class I include the tubing plug and blunt needle. For both types of accessories, FDA has found that general controls alone provide a reasonable assurance of safety and effectiveness.

(Comment 4) Two commenters noted that section III of the proposal "Policy Clarification for Classification of Certain Accessories Used in Orthopedic Surgery" was inconsistent with the risk-based approach to classification of accessories as outlined in FDARA, and classification should not be based upon whether or not an instrument is considered "general use" or "device-specific". These commenters also requested that FDA either revert back to "previous longstanding practice and treat all manual surgical instruments provided with Class II or Class III orthopedic implant systems as Class I (510(k)/PMA [premarket approval application] exempt) devices, in accordance with their current classification designation" or publish new classifications for instruments that carry a higher risk. One commenter further noted administrative challenges (e.g., tracking recalls, unique device identifier markings) for those instruments that have taken on the classification of the parent device and do not carry their own product code or regulation.

(Response) This policy clarification does not impose new regulatory requirements upon devices that had previously been cleared or approved, but rather provides transparency for the Agency's existing policy concerning classification of certain orthopedic accessories. We agree that the classification of existing accessories should and must be based upon the risk of the accessory when used as intended and the level of regulatory controls

necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of the parent device, and that the provisions in section 513(f)(6) of the FD&C Act may be appropriate to distinctly classify certain orthopedic accessory types. By clarifying how we have regulated different types of instruments for orthopedic surgery, we aimed to explain the limited scope of accessories that would be appropriate for distinct classification through mechanisms outlined in section 513(f)(6) of the FD&C Act and provide clarity regarding accessories that fit within existing class I classification regulations. If an accessory is distinctly classified, a separate classification regulation will be created. We believe this will support separate identification of the accessory distinct from the parent device.

After reviewing the comments, we continue to believe that the existing policy concerning classification of certain accessories used in orthopedic surgery should not be changed. Namely, such accessories are appropriately classified as orthopedic manual surgical instruments (§ 888.4540 (21 CFR 888.4540)) provided they do not meet the definition of a device-specific orthopedic accessory as outlined in FDA's proposal and their risk profile and regulatory controls are commensurate with that of orthopedic manual surgical instruments. Further, we continue to believe that certain device-specific orthopedic instruments have new or different risks to health compared to orthopedic manual surgical instruments, and general controls alone will not provide reasonable assurance of safety and effectiveness. These "device-specific" accessories are specifically designed for appropriate implantation or placement of the parent device and have unique dimensions, geometry, or deployment mechanisms. These accessories are critical for precise and proper placement of the parent device, and therefore, FDA considers design controls to be an important element in the regulation of such accessories to ensure appropriate compatibility between the accessory and the parent device (see § 820.30).

(Comment 5) Two commenters noted that additional guidance should be provided for manufacturers who wish to seek distinct classification of orthopedic accessories, namely "considerations for reclassification of instruments that have been previously classified through a premarket submission based on their association with a particular implant system" and "the specific information that FDA would expect to see in the

requests for instrument reclassification, preferably in a standardized submission format."

(Response) Although the question pertains to a different provision than this final classification action, we believe that clarification in this case may assist manufacturers and FDA staff for future accessory classification actions. Any manufacturer or importer may submit a request for appropriate classification of an existing accessory per section 513(f)(6)(D)(ii) of the FD&C Act. According to FDA's guidance "Medical Device Accessories:

Describing Accessories and Classification Pathways" (available at: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf>), such a request should include "[t]he proposed classification of the accessory (i.e., class I or class II), as well as the current classification, should also be clearly identified in the cover letter and/or the request. An Existing Accessory Request should include the necessary information, based on Least Burdensome principles, to establish the risk profile of the accessory when used as intended with the identified parent device. . . . Note that requests for classification of an accessory in class II must include an initial draft proposal for special controls, if special controls would be required pursuant to subsection 513(a)(1)(B) of the FD&C Act." Additional information regarding reclassification processes are described in sections 513(e) and (f)(3) of the FD&C Act. FDA recommends manufacturers submit a Pre-Submission if they have specific questions regarding such a request. More information regarding the Pre-Submission Program can be found in FDA's guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (available at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>).

(Comment 6) One commenter included several comments regarding the definition of "device-specific instrument" that we provided in section III of the proposal (the "Policy Clarification for Classification of Certain Accessories Used in Orthopedic Surgery"). The commenter noted the definition was vague and sought clarity on what is meant by "unique dimensions, geometry, and/or deployment."

(Response) To provide further clarity regarding how we interpret "unique dimensions, geometry, and/or

deployment” in the definition for device-specific orthopedic instrument outlined in FDA’s proposal, we provide the following examples to illustrate the types of instruments that we would consider to be “device-specific” and types that are not:

Examples of instruments that would be considered “device-specific”:

(1) A screwdriver that mates through a unique geometry or connection to a specially designed screw, which could not be inserted by a standard, generally available screwdriver. Such an instrument would possess a unique geometry that could not be utilized with screws of industry standard dimensions (such as cortical (HA) and cancellous (HB) bone screws per ASTM F543<sup>1</sup>). In contrast, a general use screwdriver could be used across screws “from multiple manufacturers”.

(2) An inserter instrument that is designed to specifically interface with features of the parent device to allow for insertion of the device. Such an instrument would possess unique dimensions or geometry to mate specifically with the parent device. In contrast, impactors are used to place an implant and do not require a specific interface with the parent device. These are general use instruments that could be used across multiple device types and are not based on unique dimensions, geometry, or deployment of a parent device.

Examples of instruments that would not be considered “device-specific”:

(1) Bone taps solely to create a preliminary hole to help guide subsequent placement of a screw and can be used across multiple screw types/sizes. These are not based upon unique dimensions, geometry, or deployment of a parent device.

(2) Reamers are not based upon unique dimensions, geometry, or deployment of a parent device and can be used across multiple device types to prepare a site for implantation.

In all such examples, a general use version of the instrument may still be designed based upon certain dimensions of the parent device (e.g., according to industry standard screw dimensions). However, device-specific instruments are designed specifically for use with a particular parent device based upon “unique dimensions, geometry, or deployment” of the parent device (e.g., sizes that would not be

compatible with industry standard dimensions, or specific features that are only present on the parent device).

(Comment 7) One commenter proposed an alternative definition for “device-specific instrument” as follows: “A device-specific orthopedic instrument is considered to be an accessory designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment when the instrument has an intended use or fundamental scientific technology that differs from those of the generic types of instruments either listed in the regulation or previously accepted as being contained within the regulation.”

The commenter notes that these revisions are necessary to avoid the definition applying to instruments that clearly fall within an existing class I classification regulation (e.g., § 888.4540), citing a screwdriver as being an example of such an instrument that could be interpreted, based upon the definition, to be “device-specific.”

(Response) FDA does not agree with the proposed additional text (i.e., “. . . when the instrument has an intended use or fundamental scientific technology that differs from those of the generic types of instruments either listed in the regulation or previously accepted as being contained within the regulation”). This text suggests that such instruments could fit under existing class I regulations (i.e., would exceed the limitation of exemption under 21 CFR 888.9(a) and (b)) but would subsequently be appropriately regulated under such regulation following submission of a 510(k)). However, this does not address the Agency’s position that general controls alone are insufficient to mitigate risks to health. Furthermore, the phrase “previously accepted as being contained within the regulation” is unclear.

We also disagree with the commenter’s statement that the definition as written would result in such a screwdriver being deemed device-specific, as such an instrument would not be “based upon unique dimensions, geometry, and/or deployment” of the parent device, unless the parent device (screw) was somehow unique in design (e.g., a screw head which would not fit a standard screwdriver).

(Comment 8) One commenter posed several specific scenarios to better understand circumstances under which an accessory would be deemed “device-specific,” such as whether branding makes an accessory device-specific, whether an accessory remains “device-

specific” if used with another device made by a manufacturer, or whether accessories to be used “across systems” applies to systems from the same manufacturer. Similarly, they asked if a combination of two general accessories from two different systems could still be considered a general use accessory.

(Response) In response to the comments, we are clarifying that the sole presence of a branding statement would not render an accessory “device-specific” according to this definition. An accessory for use with other devices made by a manufacturer may or may not be determined to be “device-specific,” depending on the design of the accessory. For example, an accessory designed for use for a specific system, i.e., across multiple-device sizes within the same family of devices, would be device-specific if it is designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment.

In some cases, an accessory may also be designed for use across multiple systems from the same manufacturer. Accessories that can be used across systems from the same manufacturer may or may not be considered device-specific, depending on technology, design, and configuration. For example, one manufacturer may have several systems of intervertebral body fusion devices, with inserter instruments that are specifically designed to mate with a unique feature on all devices in the systems and would therefore be considered device-specific. Such an instrument would possess unique dimensions or geometry to mate specifically with the parent device.

In contrast, the combination of two general use accessories would result in a general use accessory. This is because neither accessory has a design, geometry, and/or deployment suited to a particular device or device family.

(Comment 9) One commenter sought clarity on how the device-specific definition should be applied retroactively to previously cleared/approved orthopedic accessories.

(Response) The definition of “device-specific” was intended to clarify existing policy regarding regulation of orthopedic accessories, not to establish new policy. If a device was cleared within a 510(k) as an accessory but appropriately fits into an existing class I classification regulation based on the policy clarification, this determination can be documented to file by the manufacturer along with updating the listing accordingly.

(Comment 10) One commenter provided several comments regarding

<sup>1</sup> ASTM F543, Standard Specification and Test Methods for Metallic Medical Bone Screws. For the current edition of the FDA recognized standard referenced in this document, see the FDA Recognized Consensus Standards Database, available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

sizing templates, noting that they would meet the definition of “device-specific” but are otherwise distinctly classified in a class I classification regulation (§ 888.4800 (21 CFR 888.4800)). This commenter also included several examples of other devices (e.g., sizers, cutting guides, and trials) that would fall under this classification regulation.

(Response) In recent history, § 888.4800 has been interpreted to apply to imaging templates used to estimate proper device size prior to surgery rather than physical trials/sizers to be used in a surgical procedure. The initial classification panel identified the following risks to health associated with devices under this classification regulation: Tissue damage and adverse tissue reaction. Fracture of the device could injure surrounding tissue and, if device fragments remain in the tissue, could cause an adverse tissue reaction.

Further review in response to this comment has led FDA to reconsider the instruments that were to be subject to this classification regulation. We agree that trials or templates that are basic sizing devices for proper implant selection may be appropriately regulated under § 888.4800, despite the recent practice of regulating these trials with the parent device.

The Agency does not, however, consider cutting guides to fall within this classification regulation, as § 888.4800 specifically calls out devices that are used for “guiding the marking of tissue before cutting” but does not expressly include a physical guide to direct the orientation of a cut. These devices carry a higher risk than devices simply intended to mark tissues, as in addition to the risk associated with this classification regulation (i.e., tissue damage and adverse tissue reaction), an improper physical cut in the tissue leads to improper placement of the parent device and potential for resulting device malfunction or failure.

(Comment 11) One commenter sought clarity on the application of design controls to class I instruments that interface with higher-classification parent devices. The commenter notes that “any interface with a mating instrument (regardless of instrument classification) would be subject to design controls via requirements for the parent device.”

(Response) As FDA stated in the proposal, by regulation, design controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.30(a)(2)(ii).

(Comment 12) One commenter sought clarity as to whether a risk-based justification could be utilized in

determining if a device is an accessory to a parent device. While an instrument may have device-specific features, the risk may be commensurate with that of orthopedic manual surgical instruments.

(Response) The determination of whether a device meets the definition of an accessory is not a risk-based decision. We have outlined in FDA’s proposal why we consider devices with features specific to a parent device to pose additional risk beyond those of general use orthopedic manual surgical instruments.

(Comment 13) One commenter stated that the definition of “device-specific” instrument is not consistent with FDA’s definition of an accessory as outlined in the guidance document entitled “Medical Device Accessories: Describing Accessories and Classification Pathways.”

(Response) We do not consider the proposed definition for device-specific instrument to be inconsistent with FDA’s definition of an accessory, as device-specific orthopedic instruments are those designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment. Furthermore, the device-specific orthopedic instrument definition is derived from the definition of accessories (i.e., in that “design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or a specific system.”).

(Comment 14) One commenter notes that FDA stated in its proposal that “certain device-specific instruments are accessories and require precise technical specifications or design characteristics to function as intended to support, supplement or augment the parent device and if they are not designed appropriately could cause implant malpositioning or migration,” and, thus, “are ineligible for reclassification in class I.” The commenter sought clarity as to why other class I exempt devices would not also “require precise technical specifications or design characteristics.”

(Response) We expect that any device would have certain technical specifications or design characteristics that dictate their manufacture. However, for some devices, including device-specific orthopedic instruments, the safety, performance, and dependability of the device are critical for precise and proper placement of the parent device. Design controls, among other benefits, increase the likelihood that the design transferred to production will translate into a device that is appropriate for its

intended use, including precise and proper placement of the parent.<sup>2</sup> Therefore, device-specific orthopedic instruments require the application of design controls for reasonable assurance of safety and effectiveness.

(Comment 15) One commenter asked for examples of what “other regulatory controls” beyond design controls may be necessary to ensure compatibility, as stated in the proposal.

(Response) Another regulatory control could be, for example, premarket notification. For these devices for which verification of compatibility would be necessary, this may be evaluated through information (e.g., device description, performance testing) provided in a premarket submission.

(Comment 16) One commenter sought guidance on the type of information needed to describe a device-specific orthopedic instrument in premarket submissions, as well as guidance for manufacturers whose accessories have been reclassified under section 513(f)(6)(D)(ii) of the FD&C Act. This commenter also suggested that FDA consider classification of the orthopedic instruments as class I with design controls.

(Response) The commenter’s requests are outside the scope of this final classification action.

(Comment 17) One commenter noted that one of the proposed accessories for classification into class I is a handle to an inserter device for a class III product. They sought further clarity to determine whether handles for modular orthopedic instruments could be distinctly classified from their working end.

(Response) The referenced corneal inlay implant device is class III, and we proposed distinct classification of the associated handles into class I. Similarly, other such instrument handles associated with orthopedic devices cleared through 510(k) or PMA could be distinctly classified from the parent device using mechanisms outlined in section 513(f)(6)(D)(ii) of the FD&C Act.

(Comment 18) One commenter noted that some instruments provided in sets used during a surgery may not be considered “accessories” but are provided within these sets for ease of processing and access for the surgeon. Furthermore, some of these instruments may fall under existing class I classification regulations.

<sup>2</sup> For more information about design controls, refer to FDA’s guidance document entitled “Design Control Guidance for Medical Device Manufacturers,” available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf>.

(Response) We agree with the commenter. Many instruments in instrument sets would not be considered accessories to the device, and some accessories may already be distinctly classified in existing class I classification regulations.

### III. Policy Clarification for Classification of Certain Accessories Used in Orthopedic Surgery

In the proposal, FDA provided a policy clarification for the regulatory approach for certain accessories used in orthopedic surgery to distinguish which accessories may be candidates for classification under section 513(f)(6)(D)(i) of the FD&C Act. This policy clarification acknowledged that instruments used in orthopedic surgery span a wide range of complexity, with many “general use” instruments falling within existing class I classification regulations (e.g., § 888.4540), while other “device-specific” instruments have historically been reviewed in the same premarket submission as the parent device.

In an effort to ensure a common understanding as to which orthopedic accessories are considered “device-specific,” thereby not falling within an

existing class I classification regulation, and which may be candidates for classification under section 513(f)(6)(D)(i) of the FD&C Act, we provided the following definition: A device-specific orthopedic instrument is considered to be an accessory designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment. In these cases, design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or a specific system. FDA considers design controls (see § 820.30) to be an important element in the regulation of device-specific accessories, among other regulatory controls, to ensure appropriate compatibility between the accessory and the parent device. This excludes general use orthopedic instruments that are provided as a part of a system.

Based upon comments in response to this section of the proposal, FDA has not altered the policy clarification or definition of device-specific orthopedic instruments as previously described but has provided additional clarification and examples in the responses

discussed in section II above. FDA intends to engage with industry stakeholders on the topic to resolve additional questions regarding the existing policy or future proposals for distinct classification of accessories under section 513(f)(6)(D)(ii) of the FD&C Act.

### IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this final classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### V. Paperwork Reduction Act of 1995

This final classification action refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
“De Novo Classification Process (Evaluation of Automatic Class III Designation)” ...	De Novo classification process .....	0910–0844
800, 801, and 809 .....	Medical Device Labeling Regulations .....	0910–0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
“Medical Device Accessories: Describing Accessories and Classification Pathways for New Accessory Types.”.	Medical Device Accessories .....	0910–0823
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions .....	0910–0756

### List of Subjects

#### 21 CFR Part 876

Medical devices.

#### 21 CFR Part 878

Medical devices.

#### 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 876, 878, and 886 are amended as follows:

### PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.1080 to subpart B to read as follows:

#### § 876.1080 Gastroenterology-urology accessories to a biopsy instrument.

(a) *Identification.* A gastroenterology-urology accessory to a biopsy instrument is an accessory used to remove a specimen of tissue for microscopic examination by cutting or aspiration. This generic type of device includes a syringe for specimen aspiration and a biopsy channel

adaptor. This device does not include accessories to biopsy instruments used in other medical specialty areas.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 3. Add § 876.3500 to subpart D to read as follows:

#### § 876.3500 Penile implant surgical accessories.

(a) *Identification.* Penile implant surgical accessories are manual devices designed to be used for surgical procedures associated with the implantation of a penile inflatable implant or penile rigidity implant. This generic type of device includes the cylinder sizer, cylinder insertion tool

and needle, device placement tool, connector assembly tool, incision closing tool, corporeal dilator, tubing passer, measurement tool or tape, tubing plug, blunt needle, and hemostat shod tubing.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 4. Add § 876.4630 to subpart E to read as follows:

**§ 876.4630 Ureteral stent accessories.**

(a) *Identification*. Ureteral stent accessories aid in the insertion of the ureteral stent that is placed into the ureter to provide ureteral rigidity and allow the passage of urine. This generic type of device includes the stent positioner, wire guide, and pigtail straightener.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 5. Add § 876.5012 to subpart F to read as follows:

**§ 876.5012 Biliary stent, drain, and dilator accessories.**

(a) *Identification*. Biliary stent, drain, and dilator accessories are manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 6. Add § 876.5100 to subpart F to read as follows:

**§ 876.5100 Suprapubic catheter accessories.**

(a) *Identification*. Suprapubic catheter accessories are manual devices that are used to facilitate the placement of a suprapubic catheter. This generic type of device includes the introducer, access dilator, and peel-away sheath.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 7. Add § 876.5290 to subpart F to read as follows:

**§ 876.5290 Implanted mechanical/hydraulic urinary continence device surgical accessories.**

(a) *Identification*. Implanted mechanical/hydraulic urinary continence device surgical accessories are manual devices designed to be used for surgical procedures associated with the implantation of an implanted mechanical/hydraulic urinary continence device. This generic type of device includes the measurement tool or tape, connector assembly tool, tubing plug, incision closing tool, tubing passer, blunt needle, and hemostat shod tubing.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

**PART 878—GENERAL AND PLASTIC SURGERY DEVICES**

■ 8. The authority citation for part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 9. Add § 878.5080 to subpart F to read as follows:

**§ 878.5080 Air-handling apparatus accessory.**

(a) *Identification*. An air-handling apparatus accessory is a supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

**PART 886—OPHTHALMIC DEVICES**

■ 10. The authority citation for part 886 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 11. Add § 886.4355 to subpart F to read as follows:

**§ 886.4355 Corneal inlay inserter handle.**

(a) *Identification*. The corneal inlay inserter handle is a hand-held device intended to be used as an accessory to a corneal inlay inserter. The device extends the length of the inlay inserter to aid in delivering the inlay implant.

(b) *Classification*. Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

Dated: April 9, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-07290 Filed 4-11-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG-2019-0024]

RIN 1625-AA00

**Safety Zone; Xterra Swim, Intracoastal Waterway; Myrtle Beach, SC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain waters of the Atlantic Intracoastal Waterway in Myrtle Beach, South Carolina. This action is necessary to provide for the safety of the swimmers, participant vessels, spectators, and the general public during the swim portion of the Xterra Triathlon. This regulation prohibits non-participant vessels and persons from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

**DATES:** This rule is effective from 7 a.m. through 9 a.m. on April 14, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0024 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Justin Heck, Sector Charleston Waterways Management division, Coast Guard; telephone (843) 740-3184, email [Justin.c.check@uscg.mil](mailto:Justin.c.check@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code