

Dated: September 17, 1997.

Wilma G. Johnson,

*Acting Associate Director for Policy Planning
And Evaluation, Centers for Disease Control
and Prevention (CDC).*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0396]

Advanced Bionics™ Corp.; Premarket Approval of CLARION® Multi- Strategy™ Cochlear Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Advanced Bionics™ Corp., Sylmar, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CLARION® Multi-Strategy™ Cochlear Implant. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 26, 1997, of the approval of the application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. Sidney Jaffee, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

SUPPLEMENTARY INFORMATION: On December 29, 1996, Advanced Bionics™ Corp., Sylmar, CA 91342, submitted to CDRH an application for premarket approval of the CLARION® Multi-Strategy™ Cochlear Implant. The device is a cochlear implant and is intended to restore a level of auditory sensation to individuals with profound sensorineural deafness via electrical stimulation of the auditory nerve. The CLARION® Multi-Strategy™ Cochlear Implant is indicated for the following:

Children:

- Two through 17 years of age. If x-rays demonstrate evidence of ossification, children as young as 18 months may be implanted;
- Profound, bilateral sensorineural deafness (≥ 90 dB);
- Undergone or be willing to undergo a hearing aid trial with appropriately fitted hearing aids; and
- Lack of benefit from appropriately fitted hearing aids. In younger children, lack of benefit with hearing aids is defined as a failure to attain basic auditory milestones such as a child's inconsistent response to his/her name in quiet or to environmental sounds (Meaningful Auditory Integration Scale). In older children, lack of aided benefit is defined as scoring 0 percent on open-set word recognition (Phonetically Balanced Kindergarten Test—Word List) administered with monitored live-voice (70 dB SPL). Both younger and older children should demonstrate only minimal ability on age appropriate open-set sentence measures and a plateau in auditory development.

On May 21, 1997, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 26, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director of Clinical and Policy Review of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and

substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

*Deputy Director for Regulations Policy, Center
for Devices and Radiological Health.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0393]

Avanta Orthopaedics Corp.; Premarket Approval of Braun-Cutter Trapezo- metacarpal prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Avanta Orthopaedics Corp., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Braun-Cutter Trapezo-metacarpal Prosthesis. After reviewing the recommendation of the Orthopedics and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 19, 1997, of the approval of the application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Theodore R. Stevens, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

SUPPLEMENTARY INFORMATION: On December 24, 1996, Avanta Orthopaedics Corp., San Diego, CA 92121, submitted to CDRH an application for premarket approval of the Braun-Cutter Trapezo-metacarpal Prosthesis. The device is a finger joint metal/polymer cemented prosthesis and is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

On June 9, 1997, the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 19, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the

petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details. Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0392]

Mallinckrodt, Inc.; Premarket Approval of Albuterol®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Mallinckrodt, Inc., St. Louis, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Albuterol®. After reviewing the recommendation of the Radiological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 17, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212.

SUPPLEMENTARY INFORMATION: On September 3, 1995, Mallinckrodt, Inc., St. Louis, MO 63134, submitted to CDRH a supplemental application for premarket approval of Albuterol. The device is an ultrasound contrast agent and is indicated for use with transvaginal ultrasound to assess fallopian tube patency.

On February 24, 1997, the Radiological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On June 17, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director of Clinical and Review Policy of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for