POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are kept in file folders, card files, and cabinets; microfilm records on reels and in cabinets; microfiches in cabinets; magnetic tapes and cards in cabinets and storage libraries; and computer records within a computer and attached equipment.

RETRIEVAL:

Records are filed by name or social security number at each location.

SAFEGUARDS:

Records are stored in locked containers or secured rooms when not in use by an authorized person. Electronic records are protected by a password system.

DISPOSAL:

The Finance Division disposes of the records by shredding or burning, as scheduled in the handbook GSA Records Maintenance and Disposition System (OAD P 1820.2A).

SYSTEM MANAGER AND ADDRESS:

Director, Finance Division, General Services Administration (6BC), 1500 East Bannister Road, Kansas City, MO 64131.

NOTIFICATION PROCEDURE:

An individual inquiry should be addressed to the system manager.

RECORD ACCESS PROCEDURES:

An individual request should be addressed to the system manager. Furnish full name, social security number, address, telephone number, and approximate dates and places of employment. For the identification required, see 41 CFR part 105–64, published in the **Federal Register**.

CONTESTING RECORD PROCEDURE:

GSA rules for contesting the content of a record and appealing an initial decision are in 41 CFR part 105–64,

RECORD SOURCE CATEGORIES:

The sources are individuals themselves, other employees, supervisors, officials of other agencies, State governments, record systems GSA/HRO–37, OPM/GOVT–1, EEOC/GOVT–1, and private firms.

Dated: July 8, 1997.

John H. Davenjay,

Director, Administrative Policy and Information Management Division.

[FR Doc. 97–24881 Filed 9–22–97; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–24–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. Airways Disease in Miners—(0920–0349)—Reinstatement—A relationship between coal mining exposure and lung function loss has been demonstrated. Both smoking and coal mine dust exposure are associated with clinically important respiratory dysfunction. Their separate contributions to obstructive airway disease in coal miners appear to be additive. However, much of the apparent variation in the health risks of coal mine dust exposure remains unexplained. Miners exposed to similar levels of coal mine dust demonstrate large variations in lung function loss. Intrinsic susceptibility to the dust or some environmental factor not yet identified must be sought to explain why some individuals suffer severe lung damage and others experience stable or age related changes in lung function in response to inhalation of respirable dust.

The spectrum of respiratory disease in coal miners is certainly broad. Pneumoconiosis is widely accepted as specific to mine dust exposure. It has been observed that emphysema is more common and severe in coal miners than non-miners. Symptoms of chronic bronchitis are common in miners and the risk of their development has been related to exposure to the mine environment. Over 50% of non-smoking coal miners with identifiable airflow obstruction may have asthma. Questions that remain include: What are the predictable factors which relate variations in airflow obstruction in miners to measured respirable coal mine dust exposure? What are the specific processes responsible for lung function losses in miners?

The goals of this investigation are to: (1) Improve our understanding of the processes and mechanisms involved in the development of pulmonary diseases and accelerated lung function losses in underground coal miners and other dust exposed workers, and to further define the consequences of inhalation of coal mine and other dusts; and (2) Identify potential risk factors in the development of excessive respiratory function loss as a basis for interventions to reduce morbidity and mortality associated with respirable dust in the work place.

The data collected in this study will be used to provide a basis for improving the understanding of pulmonary disease processes in dust exposed workers, and as a basis for intervention strategies to reduce morbidity in the coal mining and possibly other industries. The total annual burden hours are 130 (259/2).

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)
Physicians	40	1	0.17
Volunteers	36	1	7.0

Dated: September 17, 1997.

Wilma G. Johnson,

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

[FR Doc. 97–25170 Filed 9–22–97; 8:45 am]

BILLING CODE 4163–18–P

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.

[FR Doc. 97–25163 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

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.