DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

# Memorandum

Date JUN 26 1997

From Deputy Director of Clinical and Review Policy
Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Advanced Bionics™ Corporation
CLARION® Multi-Strategy Cochlear Implant
for Pediatric Use - ACTION

To The Director, CDRH
ORA ________

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Kimber Richter

Kimber C. Richter, M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved X Disapproved _____ Date 6/26/97

Prepared by: Sidney Jaffee, M.D., CDRH, 6/16/97, 594-2080
James Warren, CDRH, 6/16/97, 594-2080
Harry Sauberman, CDRH, 6/16/97, 594-2080
David Segerson, CDRH, 6/16/97, 594-2080

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DOCKET NO. [                    ]

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 (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data on which CDRH based its approval and petitions for administrative review should be submitted 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 a premarket approval (PMA) application for 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. Clarion 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% 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 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 (insert date 30 days after date of publication in the FEDERAL REGISTER), 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:______________________.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1997

Mr. Jeff Greiner
President
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, California 91342-3700

Re: P960058
CLARION Multi-Strategy Cochlear Implant
Filed: December 30, 1996
Amended: January 29, February 4, April 16, April 28, May 1, May 8, May 12, May 28, June 10 and June 11

Dear Mr. Greiner:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the CLARION Multi-Strategy Cochlear Implant. This device is intended to restore a level of auditory sensation to children with profound sensorineural deafness via electrical stimulation of the auditory nerve. CLARION is indicated for the following:

- Children, 2 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
- Lack of benefit from appropriately fitted hearing aids. In younger children, lack of benefit with hearing aids is defined as 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% 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.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, the annual postapproval reports must include the results and analyses of the postapproval studies. The studies will be conducted for a minimum of three years and are designed to monitor the long-term safety and effectiveness of the CLARION Multi-Strategy Cochlear Implant. Two studies will be performed:

- Seventy-three patients, implanted at 20 of the investigational sites will have electrical threshold, dynamic range, electrode impedance and effectiveness data collected.

- Twenty to thirty children, in the postapproval study sample of 73 patients who have been part of a longitudinal language study conducted at two of the sites, will continue to be followed for expressive and receptive language abilities for the duration of the postmarket study.

The data analyses will include

- statistical trend analysis of electrode impedance; and

- statistical analysis of efficacy data; both the subset of speech intelligibility measures used during the postapproval study as described in amendment #A011, dated June 20, 1997, and the Reynell Test of expressive and receptive language ability.

Inasmuch as you have not developed or provided a detailed protocol for the language study, you must submit a PMA supplement containing the detailed protocol to CDRH within three months of approval of your original PMA. Once the PMA supplement is approved, you may begin the language study.

In addition to the reporting requirements described in the attached conditions of approval, device failure reports will be submitted to the PMA applicant for each device failure as it occurs.

Results of the long-term data must be reflected in the labeling, via a PMA supplement, when the postapproval study is completed.

Expiration dating for this device has been established and approved at two years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Sidney Jaffee, M.D. at (301) 594-2080.

Sincerely yours,

Kimber Richter

Kimber C. Richter, M.D.
Deputy Director of Clinical
and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

  (a) has not been addressed by the device's labeling or

  (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including *in vitro* diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you *shall* submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

# SUMMARY OF SAFETY AND EFFECTIVENESS DATA

## I. GENERAL INFORMATION

Device Generic Name: Cochlear Implant

Device Trade Name: CLARION™ Multi-Strategy™ Cochlear Implant System, Model 1.2.

Applicant's Name and Address: Advanced Bionics™ Corporation
12740 San Fernando Road
Sylmar, California 91342

Premarket Approval Application (PMA) Number: P960058

Date of Panel Recommendation: May 21, 1997

Date of Notice of Approval to the Applicant: June 26, 1997

The device was originally approved on March 22, 1996 (Model 1.0), Docket # 96M-0490, and on July 17, 1996 (Model 1.2) for the indication of use in postlingually deafened adults, 18 years of age or older, with profound, bilateral, sensorineural deafness (greater than or equal to 90 dBHL), who are unable to benefit from appropriately fitted hearing aids.

## II. INDICATIONS FOR USE

The CLARION™ Multi-Strategy Cochlear Implant, hereinafter referred to as CLARION, is intended to restore a level of auditory sensation to children with profound sensorineural deafness via electrical stimulation of the auditory nerve. CLARION is indicated for the following:

- Children 2 through 17 years of age. If x-rays demonstrate evidence of ossification, children as young as 18 months may be implanted.
- Children with profound, bilateral sensorineural deafness ($\geq$90 dB).
- Children who have undergone or are willing to undergo a hearing aid trial with appropriately fitted hearing aids.
- Children who are unable to 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 from a hearing aid is defined as scoring 0% on open-set word recognition (Phonetically Balanced

Kindergarten Test (PB-K) - 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.

## III. DEVICE DESCRIPTION

CLARION converts sounds in the environment into electrical code and transmits this code to auditory nerves in the cochlea. Acoustic sound waves enter the system through the microphone located in the headpiece and are transformed into an electrical signal. This signal is sent to the speech processor via cable. The speech processor converts the electrical signal into a code that has been determined through the device fitting process selecting among the choices offered by the Clarion, to be the one most useful for a given patient in achieving sound. Once processed, the code is returned to the headpiece via cable and transmitted across the skin via electromagnetic induction to the implanted device. The implanted device decodes the signal and delivers it to the array of electrodes positioned within the cochlea. The electrodes stimulate the auditory nerve fibers within the cochlea. Each electrode is programmed to receive the processed signals and is adjusted to deliver the electrical stimulation at levels appropriate for the individual. Depending on the particular signal being transmitted, specific electrodes are stimulated.

The CLARION System consists of both patient and clinician components.

**Patient Components**: Patient components include both internal and external parts: an implanted electronic device, which is surgically placed under the skin behind the ear; an external speech processor, usually carried on a belt or in a pocket; and a headpiece. Additionally, there are accessory items, such as auxiliary microphones, telephone pick-up coils, cable clips and carrying cases.

The ***implanted device*** includes a magnet, an electronic receiver/stimulator and an electrode array. Together, the electronic receiver package and electrode array are referred to as the Implantable Cochlear Stimulator (ICS). The magnet and receiver are contained in a hermetically sealed ceramic case, measuring 1.2 x 1.0 x 0.25 inches and weighing 0.39 ounces. The receiver accepts and decodes signals from the external components of the system and presents these signals to the electrode array in the cochlea.

The electrodes, composed of platinum-iridium (90:10) alloy, are housed in a silicone rubber carrier (electrode array) and extends from the ceramic case. The intracochlear electrodes are designed to be inserted approximately 25 mm into a normally patent cochlea. The electrode array is molded in a tight spiral curve and is designed to lie near the medial wall of the scala tympani. The electrode array consists of 16 spherical contacts arranged in 8 near-radial bipolar pairs.

Stimulus output circuits are capacitively coupled. They have regulated output currents from 0.5 to 2500 μA in logarithmic steps. The eight independent channels operate simultaneously, and the receiver has a processing rate of incoming signals of 13,000 samples per second at a uniform amplitude resolution of plus or minus 3.5%. With sequential stimulation, biphasic pulses are delivered at a rate of 6,500 pulses per second.

The ***speech processor*** is a miniature computer that translates the incoming analog waveform into either analog or pulsatile electrical code (depending on the strategy that is chosen). Either waveform can be programmed to operate in a bipolar or monopolar stimulation mode with simultaneous or non-simultaneous temporal distribution of the signal. The speech processor also houses patient adjustable controls, such as volume and sensitivity, and a switch for the patient to alternate between two speech coding strategies (if the patient wishes to do so). The speech processor measures 2.5 x 3.9 x 0.8 inches and is powered by a rechargeable battery pack. A fully charged battery provides an average of nine hours continuous use.

The clinician can program two different speech coding strategies into the external speech processor. The patient can switch back and forth between the two strategies. The chosen coding strategy delivers an analog or an interleaved pulsatile stimulating waveform. Either waveform can be programmed to operate in a bipolar or monopolar stimulation mode with simultaneous or non-simultaneous temporal distribution of the signal. All of these aspects of the programming of the device are controlled by the external speech processor that provides power and data to the internal receiver.

The ***headpiece*** is held in place by a magnet that aligns itself with the magnet in the implanted device. It contains a microphone that picks up sounds from the environment and sends the sounds to the speech processor via a thin cable that connects the headpiece to the speech processor. In addition to the microphone in the headpiece, an auxiliary microphone is provided, so patients can select a microphone location according to their preference.

**Clinician Components:** Clinician components include 1) the Clinician's Programmer, a hardware/software system for conducting psychophysical measurements and configuring the patient's speech processor; 2) the Portable Cochlear Implant Tester, a hand-held electronic device for performing diagnostic tests on the implanted receiver and electrodes; and 3) the Surgeon's Kit containing a specialized electrode insertion tool to assist the surgeon in the insertion of CLARION's curved electrode array.

## IV. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative treatments for profoundly deaf children include conventional hearing aids, other cochlear implants tactile devices, and the use of manual communication or other communication systems, such as cued speech. A tactile aid is an externally worn device that converts sound waves to mechanical vibrations or electrical stimuli. These vibrations or stimuli can be felt on the skin, providing an awareness of sound.

## V. CONTRAINDICATIONS (FOR WARNINGS AND PRECAUTIONS, SEE ATTACHED LABELING)

Use of cochlear implants is contraindicated in patients in whom deafness is due to lesions of the acoustic nerve or central auditory pathway. It is contraindicated in patients who present with an active or chronic middle ear infection, and in patients whose preoperative radiographic evidence indicates cochlear ossification that would prevent electrode insertion. The device is further contraindicated in patients who have an absence of cochlear development, or who present with tympanic membrane perforation.

## VI. POSSIBLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH

**Insertion of the intracochlear electrode will destroy any prior residual auditory function in the implanted ear.**

Implant patients will incur the normal risks of surgery and general anesthesia. The implantation of the ICS and electrode array involves major ear surgery which may result in infection, bleeding, numbness, inflammation or discomfort about the ear, dizziness (either transient or persistent), facial paralysis, disturbance of taste or balance, tinnitus or neck pain. If these conditions occur, they are usually temporary and subside within a few weeks of surgery. Rarely, cochlear implantation can result in injury to or stimulation of the facial nerve or in perilymph fluid leak. Inner ear fluid leak may result in meningitis.

Implantation of the internal device may cause infection that can usually be treated with conventional antibiotics, but in some instances removal of the device may be required. Skin flaps covering the implanted receiver/stimulator portion of the device may be too thick, resulting in difficulty maintaining a good connection between the internal receiver and the external transmitter. The presence of a foreign body under the skin may result in irritation, inflammation, or breakdown of the skin in the area around the implanted device and may cause extrusion of the device. Such complications may require additional medical treatment, surgery, and/or removal of the device. Failure of the implanted device could require removal, replacement or a reduction of the number of electrodes in use. Impact or trauma to the implant site could result in damage to the ICS case.

The long-term effects of chronic electrical stimulation are unknown. Such effects may include new bone growth in the cochlea or deterioration of auditory nerve fibers. These effects may preclude replacement of the electrode array or lead to deterioration of the cochlear response.

## VII. MARKETING HISTORY

Advanced Bionics Corporation was authorized to affix the CE mark (certificate of marketing approval throughout the European Union) to the CLARION system for both adults and children in December 1993. The CLARION system for adult use has been available for commercial distribution in the United States since March 22, 1996. As of May 15, 1997, 268 international pediatric patients have been implanted with CLARION in Canada, Europe, and South America. CLARION has not been withdrawn from any country for any reason related to the safety and effectiveness of the device.

## VIII. SUMMARY OF STUDIES

### A. Nonclinical Laboratory Studies

#### 1. Microbiological

The following microbiological tests were performed:

*a) Sterility Assurance*: Three half cycles of ethylene oxide sterilization was performed on ten ICS devices and three full cycles of ethylene oxide sterilization was performed on three ICS devices to verify sterilization efficacy. The test articles were inoculated with 0.5 - 1.5 x $10^{-6}$ organisms. Following cycle completion, which included seven days of incubation, the units were found to be sterile.

*b) Ethylene Oxide Residual Analysis*: Ethylene oxide, ethylene chlorhydrin and ethylene glycol were extracted by placing an ICS in purified water at room temperature for 24 hours. The residuals in the eluate were determined by gas chromatography. All residual values fell well below the allowable limit and met the required minimum for sterilant residuals.

*c) Pyrogenicity*: A Limulus Amebocyte Lysate (LAL) Kinetic-Chromogenic Assay; was conducted on one ICS article. The test article was covered with sterile non-pyrogenic water for injection and extracted in a shaker incubator for 40 to 60 minutes at 37°C to 40°C. There were no signs of pyrogenicity.

#### 2. Biocompatibility

The sponsor submitted adequate data from a series of in-vitro and in-vivo studies demonstrating the biocompatibility of the following tissue-contacting components of the device:

**ICS - Receiver/Stimulator Portion**

Alumina: The ICS utilizes a polycrystalline alumina ceramic receiver capsule to house the electronics of the device.

Titanium nickel alloy: The braze that joins the ICS ceramic receiver to the electrode is 70% titanium: 30% nickel alloy.

Niobium: The ICS's indifferent electrode is fabricated from 99.5% pure niobium metal.

Epoxy: Epoxy is utilized to encapsulate the feed-through electrical components between the electrode array and receiver portions.
Silicone: The ICS is coated with silicone, with the exception of a portion of the niobium band.

**ICS - Electrode Array Portion**

Platinum-iridium: The electrodes are comprised of 90% platinum and 10% iridium alloy.

Silicone: The electrodes are housed in a silicone rubber carrier that extends from the ICS receiver/stimulator. An additional silicone block is placed to add further protection for the electrode wires.

The ICS, with the exception of the niobium band, is coated with silicone and overlays the electrode lead as it exits the ICS, serving as a protector.

**External Headpiece Base**

The headpiece is molded from ABS resin.

**The following biocompatibility tests were conducted on the above-mentioned components.**

*a) Cytotoxicity*: A minimum essential medium (MEM) elution test evaluation of one ICS, one small and one large headpiece, and one electrode array with partial coating of Nusil MED 1137 was conducted to evaluate each of these items under the MEM testing requirements. The extract from each item immersed in MEM culture media at 37°C for 24 hours was evaluated. Test extracts and negative and positive control culture plates containing mouse fibroblast cells were incubated at approximately 37°C for 48 hours. The test articles did not produce evidence of cytotoxicity.

A minimum essential (MEM) elution test evaluation of 30 small headpiece shells glued with MEK (IPS 2354) glue was conducted to evaluate the MEK (IPS 2354) glue used to construct the small headpiece. The extract from each test article immersed in MEM culture media at 37°C for 24 hours was evaluated. Test extracts and negative and positive control culture plates containing mouse fibroblast cells were incubated at approximately 37°C for 24, 48, and 72 hours. The test articles did not produce evidence of cytotoxicity.

*b) Genotoxicity*: Normal saline extracts from a functional ICS, powered for 30 days, were prepared for use in the Salmonella Reverse Mutation Assay (Ames Test). The extract tested against five tester strains was found to be non-mutagenic.

*c) Acute Systemic Toxicity*: Saline, cottonseed oil, ethanol and polyethylene glycol extracts from an ICS were injected into groups of mice (each group consisting of five mice). The mice were observed for 72 hours. There were no signs of toxicity.

*d) Intracutaneous Toxicity*: Saline, cottonseed oil, ethanol and polyethylene glycol extracts from an ICS were injected intra cutaneously into four rabbits. The rabbits were observed for 72 hours. There were no signs of irritation in the test sites.

*e) Muscle Implantation Test*: Three ICS devices and three negative controls were implanted intramuscularly in three rabbits for 90 days. There were no adverse effects. The ICS devices did not produce significantly greater biological reactions than did the negative controls.

*f) Hemolysis*: Saline extracts from an ICS and small and large headpiece were shown to be non-hemolytic.

*g) Sensitization*: Saline and cottonseed oil extracts from an ICS, small and large headpiece, and electrodes with partial coating of Nusil MED 1137 were shown to be non-sensitizing (Magnusson & Klingman maximization method). Positive controls validated the test procedure.

h) *Primary Irritation*: Large headpiece and small headpiece test articles were applied to abraded and non-abraded skins of six rabbits. The rabbits were observed for 24 and 72 hours. The test articles did not produce skin irritation in the test sites.

*i) Corrosion*: A study utilizing a combination of eight functional and four demonstration ICS devices was conducted. The ICS devices were soaked in saline at 37°C, while delivering an output stimulus. The test used a stimulation waveform to produce a charge density of 425 $\mu C/cm^2$/phase, well beyond the maximum allowed charge density for an electrode (300$\mu C/cm^2$/phase). Analysis consisted of microscopic and scanning electron microscopy (SEM) examination, monitoring of electrode impedances, and analysis of the solution in which devices were soaked for the presence of Aluminum (Al), Nickel (Ni), Niobium (Nb), Platinum (Pt) and Titanium (Ti).

One electrode on each functional device was stimulated (3-M), and it produced lower impedance readings (1.5k $\Omega$), compared to the unstimulated electrodes (7k $\Omega$), at the 3 month test cycle. Impedance readings at the six, nine, and twelve-month test cycles were consistent with the three month results, 1.5k $\Omega$ for the stimulated electrodes, and 5.4k $\Omega$ for the unstimulated electrodes.

No detectable amount of Pt, Al, Ni or Ti was observed in the test solutions at the completion of a three, six, and nine-month test cycle. At the completion of the twelve-month test cycle, a more sensitive analysis was available and showed low levels of Pt (0.06 mg/L), Al (0.02 mg/L), Ni (0.006 mg/L), and Ti (0.025 mg/L). Trace amounts of Nb (0.836 to 1.180 mg/L) were detected in these samples. The niobium released daily by one implant (2.2µg/day) is 15 - 30% of the average dietary intake. At a dissolution rate of 2.2µg/day, 40 mg of niobium would dissolve from the band over a period of 50 years, representing a loss of 0.036 mm in thickness from the 1mm thick band. This would not affect the integrity of the case.

The SEM analysis showed no significant differences in appearance between the control and test units on the niobium band and the braze area. The stimulated electrode ball on each active unit, which was stimulated at a current density well beyond what the implant operates at, showed pitting and an irregular surface texture as compared to the non-stimulated electrodes. The absence of significant corrosion products from the device, together with the biological testing data, demonstrated biocompatibility.

**3. Electrode Insertion and Cochlear Histopathology**

The design of the CLARION electrode array resulted from a series of chronic in-vitro and in-vivo implant studies. The opportunity to study the temporal bones or auditory central nervous system of deceased CLARION patients has not presented itself at the time of this writing.

Insertion studies in human cadaver temporal bones were conducted to evaluate the incidence of traumatic damage resulting from the surgical introduction of a spiral electrode array (Ref. 1,2). These studies evaluated both the possibility of insertion trauma and the reliability of electrode contact positioning. In these studies, the restricted surgical view and approach were maintained to reflect the actual insertion process. The studies were conducted with an intra cochlear electrode array identical to the CLARION electrode array in that it was molded with a spiral shape reflecting the appropriate dimensions of the human scala tympani and incorporating a vertically oriented central rib to determine the structural characteristics of the molded insert. Microdissection of each temporal bone followed insertion of the electrode array. The trials found that surgical application of these spiral electrodes did not result in fracture of the osseous spiral lamina, tearing of the basilar membrane or observable damage to the spiral ligament. Electrode contacts varied in lateral position by an average of less than 100 microns.

## 4. Measurement of DC Levels

Direct current (DC) is potentially damaging to neural tissue. The CLARION ICS has been designed to minimize direct-current stimulation. The design utilizes ceramic capacitors that are placed in series with each of the 16 output leads.

The leakage characteristics of the series output capacitors are specified by the manufacturer to be less than 1 nA/V. For the worst-case situation within the Clarion strategies, where a compliance voltage of 7 V could be reached, this corresponds to a maximum of 7 nA of leakage current. This capacitor specification is worst-case and typical leakages are less. A test was performed, using a picoammeter, to monitor the actual direct currents that occur. These currents were found to be less than 0.1 nA on all outputs. The measurement noise level for this test was approximately 0.05 nA.

## 5. Electromagnetic Susceptibility

*a) Near-Field ICS Testing*: An ICS was placed in an electric field between two 7-cm square copper plates separated by 5 cm. The field was swept through the frequency range of 2 to 500 MHz at an electric field strength of 340 V/m. The ICS operated normally under these conditions.

An ICS was placed in a magnetic field produced by a single-turn loop. Within each of 6 frequency bands covering the frequency range of 2 to 560 MHz, the field strength was increased until the ICS stopped working. With one exception, susceptibility levels varied from 1.3 to 10.3 A/m. In the band of 10.3 to 11.1 MHz, the ICS failed at 0.03 A/m.

*b) System Testing*: A complete patient system, consisting of an ICS, Speech Processor, headpiece and cable, was tested to evaluate the effects of radiated electromagnetic fields. The ICS was immersed in saline to simulate body tissue characteristics with a monitoring system established using a fiberoptic line to exit the testing field. Testing was conducted from 10 kHz to 1 GHz at electric field strengths of 0.5 to 7.0 V/m in a shielded room. The system was required to exhibit no loss of telemetry during exposure and to function electrically at the completion of testing. The system passed the electromagnetic susceptibility test, including the range used by cellular phones (800-900 MHz). The system was user tested with home cordless telephones, analog cellular telephones, and digital cellular telephones. None of the technologies caused device malfunction or failure, although the implant user experienced a pulsing interference with a digital cellular telephone. The field strengths emitted by the cellular telephones used by the implant users were not reported.

## 6. Environmental Stress and Wear

A battery of engineering tests was performed on a group of ICSs at the component, sub-assembly, device and system level. Each sample was tested before and after each test. At the completion of each test, the characteristics of each element were measured and found to be the same as pre-test output characteristics.

*a) Life Test - Accelerated High Temperature:* Eleven ICS chips (VLSI) and 5 ICS hybrid assemblies were subjected to over 1,000 hours of life testing at a temperature of 125°C. Units were electronically tested at weekly intervals. At the completion of the test, all units were tested for electrical functionality. All units passed.

*b) Helium Leak (Hermeticity):* All ICS units were 100% tested at the time of manufacture for hermeticity (this practice continues as part of the applicant's Good Manufacturing Practices). Each unit was placed in a ceramic case assembly and welded in an atmosphere of an inert gas mixture that included helium. Prior to final sealing, each feed-through, feed-through/header assembly, ceramic case and case band assembly was checked individually for hermeticity (leak rate less than $1 \times 10^{-9}$ cc-atm/s of helium). Only units that passed the helium leak test proceeded to final production devices.

*c) Electrostatic Discharge (ESD):* Two speech processors (SPs), Clinician's Programmers (CPs) and Battery Chargers (BCs) were subjected to ESD testing at levels of 5, 10, 15, 20 and 25 kV peaks. After each shock, devices were evaluated for both soft (loss of performance) and hard (component damage) failures. Devices were required to exhibit no soft failures up to 15kV and no hard failures up to 25kV. All units passed.

*d) Temperature Shock/Cycling:* Ten ICS assemblies (five with attached electrodes, five without electrodes), five SPs, five CPs and five BCs were subjected to thermal shock/cycling for 10 cycles. One thermal cycle was comprised of placing the device in a preheated chamber for the designated minimum time and then immediately transferring the device into a chamber that had been pre-cooled for the minimum designated time, as shown in Table 1.

**Table 1**

| | Chamber 1 | Chamber 2 |
|---|---|---|
| ICS | 125°C(+10°C/-2°C)<br>5 minutes | -55°C(+2°C/-10°C)<br>5 minutes |
| SP | 65°C(+0°C/-5°C)<br>25 minutes | -40°C(+0°C/-5°C)<br>25 minutes |
| CP | 65°C(+5°C/-0°C)<br>25 minutes | -40°C(+0°C/-10°C)<br>25 minutes |
| BC | 65°C(+0°C/-5°C)<br>25 minutes | -40°C(+0°C/-5°C)<br>25 minutes |

At the completion of testing, the ICS (receiver/stimulator) was evaluated for hermeticity. All devices were visually inspected and tested for electrical functionality. All devices passed.

*e) Temperature Storage*: Five of each device were subjected to high and low temperatures, as shown in Table 2, for 96 hours at each temperature:

**Table 2**

| [illegible] | HIGH degree Centigrade | LOW degree Centigrade |
|---|---|---|
| ICS | +60° | -10° |
| SP | +60° | -25° |
| CP | +60° | -25° |
| BC | +60° | -25° |

At the completion of the test, the devices were electrically tested for functionality. All devices passed.

*f) Humidity Exposure*: Five SPs, CPs, and BCs were subjected to 90% - 95% relative humidity at 40°C for 96 hours. Devices were evaluated at the completion of the testing for corrosion and electrical functionality. All devices passed.

*g) Mechanical Vibration*: Two ICSs, SPs, CPs, and BCs were subjected to sinusoidal vibration at a level of 10G (2G for the CPs) over a frequency sweep of 5Hz to 2000Hz to 5Hz on three axes. Devices were electronically tested for functionality at the completion of the testing. All devices passed.

*h) Mechanical Drop*: Two SPs, and two BCs were dropped from 36-inch heights onto linoleum covered concrete. At the completion of testing, devices were visually inspected for damage and tested for electrical functionality. All devices passed.

*I) Mechanical Shock Testing*: Five ICSs were subjected to mechanical shock testing using a shock level of 100G (±25G), half-sine pulse, with a pulse duration of 5 ms (±2 ms). One shock was applied in each X, Y, and Z axis with complete electrical testing after each shock. After testing was completed, the hermetic seal was evaluated and physical integrity was examined under 30X magnification. No physical anomalies were identified, hermeticity was maintained and electrical performance was verified.

Five SPs and were subjected to shock testing using a shock level of 100Gs (+/-25G), half-sine pulse, with a pulse duration of 0.5 ms to 1.0 ms. One shock was applied in each of six mutually perpendicular axes. At the completion of testing, devices were visually inspected and tested for electrical functionality. All units passed.

*j) Shelf Life:* A long-term evaluation was conducted on two ICSs over the two years and eight months since their date of manufacture. Original electrical testing included a voltage level test and a standard electrical functionality test. No appreciable changes in performance occurred in the two devices since the date of manufacture.

*k) Shipping Damage:* Three ICS, SP, CP and BC were packaged for standard shipment and subjected to the NTSA Project 1A Test Program. Upon completion of the testing and inspection of the packaging, devices were tested for total functionality and visually inspected for damage. All devices were fully functional at the completion of the test.

*l) Electrode Array:* Four electrode arrays were subjected to the following testing:

> Handling/Pull: Six drops of the ICS in six different positions while inserted in an electrode insertion tool (i.e., the ICS was dropped with the fantail portion pointing downwards, with the back portion pointing downwards, with the underside facing downwards, with the front side facing downwards, and then with each of the two side edges pointing downwards).
>
> Electrode Twist: Fifty cycles of twisting the electrode array two full turns in each direction.
>
> Electrode Flex: Fifty cycles of flexing the spiral end of the array over the fantail portion.
>
> Mechanical Performance: Ten cycles of insertion and re-insertion of the electrode array into the electrode insertion tube.

Fantail Flex: The purpose of the fantail flex test was to compare the flex life characteristics of the model 1.2 ICS pediatric electrode assemblies in the fantail region with the model 1.0 ICS adult electrode fantails (The models 1.0 and 1.2 Implantable Cochlear Stimulators (ICS) have been approved for use in adult patients. The model 1.2 ICS for pediatric use is the subject of this PMA application).

The fantail portion of 5 model 1.2 electrode arrays and five model 1.0 electrode arrays were flexed (5/16 inch displacement) at a rate of approximately 220 cycles/minute while the ICS was held stationary. Because of its offset location in relation to the ICS, model 1.2 was tested on both the inner and outer sides with the flex point located 3/8 inch (least severe position) and 1/8 inch (most severe position) from the ICS fantail junction. The fantail was flexed until wire continuity was lost or until 2,000,000 cycles were reached.

Flexed in the "outer" direction, the flex life durability of model 1.2 and model 1.0 were comparable (1.2 million cycles to failure in the least severe test position and 33 thousand cycles to failure in the most severe test position. The flex life durability of model 1.2 was less than model 1.0 when the 1.2 fantail was flexed in the "inner" direction. This is due to the offset design of the fantail in contrast to the centered location of the model 1.0 fantail.

7. **Failure Modes and Effects Analysis**

The predicted reliability of the ICS, SP and headpiece assembly was assessed utilizing failure modes and effects analysis (FMEA). Analyses did not reveal the presence of a failure that could lead to a life-threatening or hazardous situation.

As of February 28, 1997, 443 patients with ICS devices have been implanted worldwide. There have been 29 device failures (6.55% of 443 patients). Seven of the device failures were due to electrode wire damage in the fantail region of the ICS and 20 failures were due to ICS ceramic case trauma/fracture.

## B. Clinical Investigations

### 1. Patient Inclusion and Exclusion Criteria

**Inclusion Criteria:**

Children, 2 through 17 years of age

Bilateral, profound sensorineural hearing loss (≥90 dB HL)

Had worn appropriately fitted hearing aids for at least 6 months (if deafness was secondary to meningitis and there was radiographic evidence of cochlear ossification, a hearing trial of only three months was required and the age at implantation was lowered to 18 months)

Negligible benefit from conventional hearing aid amplification (defined as scoring 0% on an open-set word recognition (PB-K Word List) for children with the language skills to take that test. For younger children, lack of aided benefit is defined as not progressing past a score of 2 on the MAIS test questions 3, 5 and 6

Enrolled in a rehabilitation programmed that emphasized auditory/oral development

English as the primary language spoken in the home.

**Exclusion Criteria:**

Medical or general health conditions that presented risks to surgery

Radiographic evidence of cochlear deformity that would prevent electrode insertion

Acute middle ear pathology

Mental retardation

Less than six-months elapsed since the onset of deafness and hearing aid use

Parental lack of facility with English

Hearing aid benefit scores exceeding those established in the inclusion criteria.

Enrollment in a rehabilitative/educational program that did not promote the use of auditory and speech skills.

**2. Study Period and Study Population**

Clinical investigation of CLARION in the pediatric population was initiated in March 1995 and the first patient was implanted in April 1995. As of the date of the Ear, Nose and Throat Devices Panel meeting on May 21, 1997, the CLARION clinical study period in children totaled approximately 25 months.

All implanted patients satisfied protocol inclusion and exclusion criteria. Implantations were equally divided between males and females. The mean age at onset of deafness in the implant ear was eight months. The mean age at implantation was 5.3 years (range 2 years to 17 years). Ninety-eight percent (98%) of the study sample was prelingually deafened (onset of deafness at or before age 3).

Clinical data reflects patient information up to May 15, 1997, and is included in the summary of safety and effectiveness data.

The analyses of effectiveness considers the 73 U.S. patients who had completed their six (6) month audiological evaluations as of October 31, 1996 (the cut-off date used for submission of the PMA in December 1996).

**Investigators and Number of Investigational Subjects**

Clinical investigation of CLARION in children was initially approved at 20 investigational centers. The CLARION study was expanded to include a total of 35 investigational centers.

The clinical investigation consisted of two study groups. The primary study sample consisted of deaf children who had never used a cochlear implant. The secondary study group consisted of children, who had been previously implanted with a device produced by a manufacturer other than Advanced Bionics and who had experienced internal device failures. Results from these two groups were pooled for analysis of safety, but the results were not pooled for the analysis of effectiveness.

### 3. Evaluation Measures

Device effectiveness was measured using a within-subject, repeated measures design with each patient serving as his or her own control. A range of improvement in auditory communication skills was expected with use of the implant. No consensus exists regarding the level of communication skills or the exact amount of improvement that constitute clinical significance. Previous experience with implants has shown that any improvements in communication skill beyond that expected by chance or guessing may be meaningful and significant to the patient. The design of the clinical trial and statistical methods employed were based on this assumption.

Preoperatively, all patients were administered a series of speech perception tests while wearing hearing aids. The same audiological tests were administered at regular intervals postoperatively (i.e., three, six, and twelve months; semi-annually) to measure performance over time. Preoperative scores served as a control condition for within-subject evaluation of efficacy claims.

Five categories of audiological outcome measures were used to assess device efficacy according to the following five study end points (or categories of benefit):

1. Awareness of speech and sound

2. Use of speech and sound in everyday situations

3. Perception of speech patterns

4. Closed-set word identification

5. Open-set speech recognition

For some outcome measures, two levels of test difficulty were used. Level 1 tests were administered to all children 3 years of age and younger. Level 2 tests were administered to all children 7.0 years of age and older. Children aged 4 though 6 years were administered a screening test to assess basic vocabulary skills to determine if Level 1 or Level 2 tests were most appropriate. Based on the results of the screening test, children aged 4, 5, and 6 were assigned to either Level 1 or Level 2 testing.

The mean age at implantation for the children tested on Level 1 measures was 3 years, 3 months (range = 19 months to 6 years). The mean age at implantation for the children tested on Level 2 measures was 9 years, 6 months (range = 4 to 17 years). All tests were administered in the sound-only condition (i.e., without lipreading) using un-monitored live-voice presentation. The outcome measures, summarized by test level, are shown in the following table.

<table>
<tr><th colspan="2">AWARENESS OF SPEECH & SOUND</th></tr>
<tr><td colspan="2">Level 1 and Level 2<br>Warble-tone and Speech Stimuli Presented in the Soundfield</td></tr>
<tr><th colspan="2">USE OF SOUND & SPEECH IN EVERYDAY SITUATIONS</th></tr>
<tr><td colspan="2">Level 1 and Level 2<br>Meaningful Auditory Integration Scale (MAIS)<br>Meaningful Use of Speech Scale (MUSS)</td></tr>
<tr><th colspan="2">PERCEPTION OF SPEECH PATTERNS</th></tr>
<tr><td>Level 1<br>Early Speech Perception Test: Pattern Perception subtest (Low verbal version)</td><td>Level 2<br>Early Speech Perception Test: Pattern Perception subtest (Standard version)</td></tr>
<tr><th colspan="2">CLOSED-SET WORD IDENTIFICATION</th></tr>
<tr><td>Level 1<br>Early Speech Perception Test: Spondee Word subtest (Low verbal version)<br><br>Early Speech Perception Test: Monosyllable Word subtest (Low verbal version)<br><br>Minimal Pairs Test (Modified - 40 items)</td><td>Level 2<br>Early Speech Perception Test: Spondee Word subtest (Standard version)<br><br>Early Speech Perception Test: Monosyllable Word subtest (Standard version)<br><br>Minimal Pairs Test (Original - 80 items)</td></tr>
<tr><th colspan="2">OPEN-SET SPEECH RECOGNITION</th></tr>
<tr><td colspan="2">Level 1 and Level 2<br>Glendonald Auditory Screening Procedure: Words and Sentences<br>Phonetically Balanced-Kindergarten Test: Phonemes and Words</td></tr>
<tr><td>Level 1<br>Mr. Potato Head: Words and Sentences</td><td>Level 2<br>Common Phrases: Words and Sentences</td></tr>
</table>

## 4. Results of Testing

Statistical analyses were performed to determine the reliability of each preoperative to postoperative comparison on each measure.

Critical improvement scores were used in the analyses of the percentage of patients who exhibited significant improvement as a result of treatment with CLARION for each efficacy claim. Claims based on improvement are for the 73 patients who have completed the six (6) month postoperative audiological evaluation as of October 31, 1996.

Critical improvement scores are defined as the smallest amount of improvement in performance that can be detected with a statistical power of 0.08 when alpha = 0.05.

Performance on the outcome measures is expressed as the number, and percentage of patients who achieved a postoperative score that exceeded either chance or their preoperative score (if the preoperative score was above chance) by the critical improvement score.

### a) Objective: Use of Sound in Everyday Situations.

Use of sound in everyday situations was assessed with the Meaningful Auditory Integration Scale (MAIS). The MAIS is a parent-report scale that assesses the auditory skills of a child as observed by the parents in everyday situations. During a structured interview, information is obtained from the parent about the frequency with which the child demonstrates a set of 10 different behaviors in everyday situations. For each of the 10 behaviors, specified in a set of questions or probes, a rating is assigned, based on the frequency of occurrence of the target behavior: 0 = never, 1 = rarely, 2 = occasionally, 3 = frequently, and 4 = always. Strict scoring criteria have been developed for the MAIS to ensure uniformity among examiners in scoring the parents' responses. Inter-rater reliability is high (i.e., .90). Results are expressed in terms of the percentage of patients who "frequently" or "always" demonstrated the target behavior.

1. Preoperatively, with hearing aids, 11% of the children frequently or always responded to their name in quiet. Postoperatively, with CLARION, 90% of the children frequently or always responded to their name in quiet (n=73).

2. Preoperatively, with hearing aids, 3% of the children frequently or always responded to their name in noise. Postoperatively, with CLARION, 52% of the children frequently or always responded to their name in noise (n=73).

3. Preoperatively, with hearing aids, 7% of the children frequently or always alerted to environmental sounds. Postoperatively, with CLARION, 78% of the children frequently or always alerted to environmental sounds (n=73).

4. Preoperatively, with hearing aids, 10% of the children frequently or always recognized sounds in the home or school environment. Postoperatively, with CLARION, 62% of the children frequently or always recognized sounds in the home or school environment (n=73).

5. Preoperatively, with hearing aids, 10% of the children frequently or always were able to discriminate between the voices of two speakers. Postoperatively, with CLARION, 55% of the children frequently or always were able to discriminate between the voices of two speakers (n=73).

**b) Objective: Use of Speech in Everyday Situations.**

Use of speech in everyday situations was assessed with the Meaningful Use of Speech Scale (MUSS). The MUSS is a parent-report scale that assesses the speech production skills of a child as observed by the parents in everyday situations. During a structured interview, information is obtained from the parent about the frequency with which the child demonstrates a set of 10 different behaviors in everyday situations. For each of the 10 behaviors, specified in a set of questions or probes, a rating is assigned, based on the frequency of occurrence of the target behavior: 0 = never, 1 = rarely, 2 = occasionally, 3 = frequently, and 4 = always. Strict scoring criteria have been developed for the MUSS to ensure uniformity among examiners in scoring the parents' responses. Inter-rater reliability is high (i.e., .99). Results are expressed in terms of the percentage of patients who "frequently" or "always" demonstrated the target behavior.

6. Preoperatively, with hearing aids, 29% of the children frequently or always varied the rhythm of their vocalizations. Postoperatively, with CLARION, 52% of the children frequently or always varied the rhythm of their vocalizations (n=73).

7. Preoperatively, with hearing aids, 36% of the children frequently or always were willing to use speech only to communicate about a familiar topic. Postoperatively, with CLARION, 62% of the children frequently or always were willing to use "speech only" to communicate about a familiar topic (n=73).

8. Preoperatively, with hearing aids, 32% of the children frequently or always were willing to use speech only to communicate about an unfamiliar topic. Postoperatively, with CLARION, 55% of the children frequently or always were willing to use "speech only" to communicate about an unfamiliar topic (n=73).

**c) Objective: Closed-Set Word Identification.**

**Closed-set word identification** was measured with the Monosyllable Word Identification subtest of the Early Speech Perception Battery. The performance of the younger patients (Level 1) was assessed with the Low Verbal version, whereas the performance of the older patients (Level 2) was assessed with the Standard version. The Low Verbal version consists of sets of 4 objects from which the child must choose the correct answer. The test consists of a total of twelve items (three repetitions of each of the four test items in random order). The Standard version consists of a picture card with 12 items from which the child must choose the correct answer. The test consists of 24 items (two repetitions of each item).

**9.** Fifty-one percent (51%) younger children demonstrated improvement in the identification of single syllable words when presented with a choice of four objects compared to pre-implant performance with hearing aids. The patients in the study sample (n = 45) demonstrated a range of performance postoperatively. Eight children (18%) identified 100% of the words. Nineteen children (42%) identified 75% or more of the words. Twenty-three children (51%) identified 50% or more of the words. Twenty children (44%) were assigned a chance score of 25%.

**10.** Seventy-nine percent (79%) of the older children demonstrated improvement in the identification of single-syllable words when presented with a list of twelve words compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Six children (21%) identified 100% of the words. Thirteen children (46%) identified 92% or more of the words. Twenty-two children (79%) identified 54% or more of the words. Twenty-four children (86%) identified 20% or more of the words. Four children (14%) identified less than 20% of the words.

**d) Objective: Open-Set Speech Recognition.**

The Phonetically Balanced-Kindergarten test (PB-K) was used to assess **open-set phoneme (i.e., speech sounds) recognition** in both the younger (Level 1) and older (Level 2) patients. The PB-K test consists of phonetically balanced monosyllabic words based on the vocabulary of five-year old children with normal hearing. Half-lists of 25 words were used in the CLARION pediatric study. Performance was scored on the basis of the number of phonemes (n =70) correctly identified in each half-list of words.

**11.** Forty-two percent (42%) of younger children demonstrated improvement in the recognition of speech sounds (i.e., vowels and consonants) compared to pre-implant performance with hearing aids. The patients in the study sample (n = 45) demonstrated a range of performance postoperatively. Seven children (16%) recognized 50% or more of the speech sounds. Twenty children (44%) recognized 20% or more of the speech sounds. Twenty-five children (56%) recognized less than 20% of the speech sounds.

**12.** Seventy-nine percent (79%) of older children demonstrated improvement in the recognition of speech sounds (i.e., vowels and consonants) compared to pre-implant performance with hearing aids. The patients in the study sample (n =28) demonstrated a range of performance postoperatively. Three children (11%) recognized 90% or more of the speech sounds. Nine children (32%) recognized 75% or more of the speech sounds. Eighteen children (64%) recognized 51% or more of the speech sounds. Seven children (25%) recognized less than 20% of the speech sounds.

**Open-set sentence recognition** was assessed in the younger (Level 1) patients with the Mr. Potato Head task. The task involves the use of the toy, Mr. Potato Head, and the 24 parts that accompany it. The task assesses recognition of 10 simple phrases or commands (e.g., "Put a hat on Mr. Potato Head"). Because there are a large number of response alternatives, the difficulty of the task is considered comparable to that of an open-set test administered to young children with limited cognitive and linguistic skills.

**13.** Thirty-one percent (31%) of younger children demonstrated improvement in the recognition of sentences compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Six children (13%) recognized 70% or more of the sentences. Ten children (22%) recognized 50% or more of the sentences. Fifteen children (33%) recognized 20% or more of the sentences. Thirty children (67%) recognized less than 20% of the sentences.

**Open-set sentence recognition** was assessed in the older (Level 2) patients with the Common Phrases test. The test consists of 6 lists of 10 items. One list of 10 items was presented at each test interval. Performance was scored in terms of the number of complete phrases or sentences correctly recognized.

**14.** Seventy-nine percent (79%) of older children demonstrated improvement in the recognition of sentences compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Six children (21%) recognized 100% of the sentences. Nine children (32%) recognized 90% or more of the sentences. Fifteen children (54%) recognized 60% or more of the sentences. Twenty-four children (86%) recognized 20% or more of the sentences. Four children (14%) recognized less than 20% of the sentences.

**Open-set word recognition** was assessed with the Mr. Potato Head task in the younger (Level 1) patents. Performance was scored in terms of the percentage of key words (n=20) identified.

**15.** Thirty-three percent (33%) of younger children demonstrated improvement in the recognition of words compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Five children (11%) recognized 80% or more of the words. Thirteen children (29%) recognized 50% or more of the words. Sixteen children (36%) recognized 20% or more of the words. Twenty-nine children (64%) recognized less than 20% of the words.

**Open-set word recognition** was assessed with the PB-K test in the older (Level 2) patients. Performance was scored in terms of the percentage of words (25-word, half lists) correctly identified by the patients.

16. Sixty-eight percent (68%) of older children demonstrated improvement in the recognition of single syllable words compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Eight children (29%) recognized 52% or more of the words. Sixteen children (57%) recognized 20% or more of the words. Twelve children (43%) recognized less than 20% of the words.

## C. Summary of Safety Data

The following is a discussion of the anticipated and unanticipated adverse events that occurred during the clinical study using the Clarion Multi-Strategy Cochlear Implant.

As of May 15, 1997, 510 pediatric patients had been implanted with CLARION worldwide. The patient population consists of 242 subjects in the United States and 268 patients in Canada, Europe and South America.

### 1. Anticipated Adverse Events

#### a) Vertigo and Tinnitus

In most cases the presence of tinnitus could not be reliably assessed because of the limited cognitive and linguistic skills of the patients. Three patients reported tinnitus preoperatively and continued to experience tinnitus postoperatively, apparently unrelated to implantation.

Subjective reports of dizziness were monitored, but the presence of dizziness could not be reliably assessed in most cases because of the limited cognitive and linguistic skills of the patients. Postoperative dizziness was reported in two patients. One patient reported mild-to-moderate dizziness in the immediate postoperative period which was subsequently resolved. The second patient reported dizziness 3 an d 6 months postoperatively. The dizziness was not present in the immediate postoperative period nor at the time of initial stimulation. Neither patient required medication to control the dizziness.

#### b) Loss of Residual Hearing

For most patients, insertion of the intracochlear electrode array resulted in the loss of any residual hearing in the implanted ear.

#### c) Facial Nerve Stimulation

One patient experienced facial nerve stimulation when the device was initially programmed. The case was resolved by re-programming the device.

d) **Minor Surgical Complications**

Three patients experienced fever following surgery. The conditions resolved spontaneously or with minimum treatment, without surgical intervention.

Three patients experienced irritation over the implant site. The conditions resolved spontaneously, without treatment or surgical intervention.

Two patients reported pain in the area of the implant site. The conditions resolved spontaneously, without treatment or surgical intervention.

2. **Unanticipated Adverse Events**

a) **Medical Complications - Infection (6 patients)**

Two patients developed postoperative infections that required surgical intervation.

A patient developed an upper respiratory infection with acute otitis media approximately 10 days after surgery. He was hospitalized and administered I.V. antibiotics, but fluid developed under the wound. The flap was raised and the implant site was irrigated. The flap was then debrided, closed, and drainage applied. The complication has been resolved and no further problems have been experienced by the patient. The device remained functional throughout the course of his illness.

One patient developed an infection at the implant site as a result of incorrect placement of the electrode array. The patient was re-implanted.

Three other patients experienced middle ear infection postoperatively. The conditions resolved spontaneously without surgical intervention.. Another patient experienced middle ear infection at the time of implantation that also resolved without surgical intervention.

b) **Medical Complications - Facial Nerve Paralysis/Weakness (3 patients)**

One patient was found to have complete right facial paralysis. During her initial operative procedure, in order to identify the round window to drill the cochleostomy, the surgeon had to enlarge the facial recess by removing most of the bone over the facial nerve on the middle ear side. No evidence of trauma was indicated from the facial nerve monitor during the procedure. The implant was inserted without difficulty and all ICS diagnostic tests were normal and impedance values were within normal range. Postoperatively, the patient was found to have complete right facial paralysis. She was placed on a high dose steroid regimen and scheduled for exploratory surgery. Just prior to the scheduled exploration, she was found to have gained some minimal spontaneous facial nerve function and surgery was canceled. The patient was seen four days later and at that time, no voluntary movement was noted and electrical testing showed that the nerve was no longer able to be stimulated. During exploratory surgery, it was found that the electrode lead was pressing on the nerve. The surgeon, therefore, repositioned the electrode to relieve the pressure on the facial nerve. The facial nerve is intact and the patient has done well since her surgery.

Another case of facial paralysis occurred in a 17-month old patient. At surgery, the facial nerve was found to be in an anomolous position and was repositioned to allow better access to perform the implantation.

Facial nerve weakness was observed 48 hours following surgery in the third patient, and was attributed to post-surgical edema. Three months postoperatively, the facial nerve weakness was resolved and facial nerve function was reported to be normal.

c) **Device Failures (30)**

There have been thirty (30) occurrences of unanticipated events as a result of device failures. Device malfunction include two primary modes of failure, electrode damage (7 events), and damage to the ICS case (19 events).

Four other failures occurred. One failure is related to manufacturing and the cause of another failure is listed as unknown. The cause of the other two failures are still under investigation and the patients have not been explanted. The other twenty-eight (28) events required revision surgery.

***Case Damage (19)***

ICS cases implanted during the pediatric clinical study were obtained from two manufacturers, using the same material (alumina ceramic) but different manufacturing processes. One manufacturer used a process called isopress, in which components were manufactured from spray dried powder compacted under high pressure. The other manufacturer used injection molding, in which a homogeneous mixture of ceramic material is encased in a thermoplastic binder system.

Advanced Bionics suspended the pediatric IDE study May 23, 1996 to investigate several ceramic case fractures. In almost every incident of ICS case damage, the patient either fell or sustained an impact at the implant site. Clinical data and engineering analyses indicated that cases manufactured by the isopress process were weaker than cases manufactured by the injection molding process. Testing showed that the injection molded cases withstand, on average, a 50 pound higher peak compression force than isopress cases. Based on this information the pediatric trial was, with CDRH concurrence, resumed on August 9, 1996 using only the injection molded case. Advanced Bionics has discontinued use of cases manufacured by the isopress process.

Quality assurance procedures have been established to reduce the probability of manufacturing injection molded devices whose cases do not meet the strength specification. Labeling includes the warning that protective headgear should be worn when engaged in physical activities in which there is a possibility of direct trauma to the implant site.

Sixteen (16) patients implanted with cases manufactured by the discontinued isopress process experienced a device failure as a result of damage to the ceramic case. All 16 patients have been re-implanted with a new device.

As of May 15, 1997, 321 patients have been implanted with cases manufactured by the currently used injection molding process. Eighty-two (82) of the 321 patients have been implanted for over one year. Three (3) patients implanted with the cases experienced a device failure as a result of damage to the ceramic case. These failures were the result of a direct impact to the implanted device. There was no effect associated with the aging of the ceramic material or the duration of the implantation. All three patients have been explanted and re-implanted with a new device.

Because cases manufactured by the isopress process have been discontinued, labeling for the CLARION® Multi-Strategy Cochlear Implant, lists device failures only for cases manufactured by the injection molded process

***Electrode Failure (7)***

In all cases of electrode damage, the surgical technique used in implanting these devices did not adhere to the recommended methods. As a result, the devices were not secured or stabilized to minimize movement. It was found that when the ICS undergoes sudden or repetitive movements perpendicular to its horizontal axis while the fantail is simultaneously constrained or fixed in place, the fantail wires are subject to breakage due to combination of tensile and shear forces. The data demonstrate that electrode damage occurred in the population where devices were not stabilized through the use of recommended surgical technique. Further, there have been no failures due to electrode damage in the patient population that were implanted with surgical methods recommended for CLARION. The CLARION surgical guidelines are clearly outlined in the "Surgeon's Manual," and surgical training sessions. As a result of these electrode failures, Surgical Bulletin #2, dated March 8, 1996, was distributed. The Bulletin was intended to reinforce and emphasize the recommended surgical procedures and techniques. On April 3, 1996, another surgical bulletin describing the electrode damage failure mechanism and illustrating the appropriate surgical technique was distributed to prevent additional incidents of wire breakage. Patients with devices implanted with the correct surgical technique remain free of electrode damage failures.

**Other Device Failures (4)**

Two patients experienced device failure due to causes yet to be determined and will require surgery to replace the devices. Both patients were implanted with cases manufactured by the injection molding process.

One patient experienced electronic device failure and required surgery to replace the device.

One patient experienced device failure due to an undetermined cause and required surgery to replace the device.

3. **Performance Degradation Over Time**

Adverse effects on audiological performance from chronic electrical stimulation were not observed in the investigation; i.e., there was no evidence of deterioration in performance with continued use of the implant up to 12 months.

Electrical dynamic range, a measure of the difference between the amount of current needed to produce the softest sound the patient can hear and the amount of current needed to produce the loudest sound the patient judges to be comfortable, was analyzed on a sample of patients and showed a pattern of increasing dynamic range. Electrical impedance changes were also evaluated for the electrodes in each patient. No significant changes were recorded.

d) **Bone Growth**

Bone growth in cochlear implant patients may be caused by electrical stimulation and/or surgical trauma. An indication of bone growth would be a degradation in audiological performance with time, presumably a rise in hearing threshold or in the electrical impedances of the electrodes. As indicated above, audiological performance with the implant remained constant or improved over the 12 months of the clinical study. No changes were noted in electrode impedance measurements.

## IX. CONCLUSIONS DRAWN FROM THE STUDIES

The nonclinical and clinical data provide reasonable assurance that the CLARION Multistrategy Cochlear Implant System is safe and effective for its intended use, as stated in the approved labeling. See attachment B.

## X. PANEL RECOMMENDATIONS

At an advisory meeting held on May 21, 1997, the Ear, Nose and Throat Devices Panel. recommended that Advanced Bionics Corporation's PMA for the CLARION be approved with conditions. These conditions included changes to the device labeling, required training for the surgeon and the audiologist, and a postapproval study.

**Labeling:** The Panel recommended that the labeling be reworded to provide clearer meaning to parents. The Panel also recommended that the labeling fully inform parents concerning three (3) device failures that have occurred in patients implanted with the currently manufactured ceramic case, as a result of a child hitting his or her head in the area of the device. The cause of two other recent case failures are under investigation.

**Required Training:** The Panel recommended that physicians who use the device in the pediatric population be trained in the proper surgical placement of the device to avoid fractures of the electrode fantail. The Panel also recommended that audiologists be trained in the techniques required to assess implant candidacy in the pediatric population and to program the speech processor.

The Panel also recommended required training for audiologists in the evaluation of implant candidates and in the programming of the device. The Panel noted that the programming of the device is highly technical. If the audiologist is not well versed in the use of the programming software, optimal patient results will not be obtained. Further, if an audiologist is not utilizing current hearing aid fitting procedures, children who could obtain more benefit from conventional amplification may not do so.

**Postapproval Study:** Although no change in threshold, comfort level, dynamic range, and impedance was noted in the pediatric population for the duration of the clinical trial, the CLARION cochlear implant uses a higher stimulation rate and a higher total charge than the other currently marketed cochlear implant. Because childhood growth and development may impact safety and effectiveness in ways that cannot be predicted from adult long-term studies, the Panel recommended a postapproval study for a period of up to five years for all of the U. S. patients in the PMA study.

In addition to a study to monitor the long-term safety and effectiveness of the device, the Panel recommended that Advanced Bionics include a test of language development. The Panel noted that, with the rapid improvement in cochlear implant technology over the last ten years and the improvement in speech reception ability obtained with a new generation of cochlear implants, it was time to initiate studies to determine if improvement in speech reception ability correlates with improvement in language skills over time for profoundly deaf children.

## XI CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) DECISION

CDRH concurred with the Panel's recommendation that the PMA be approved with labeling changes, the imposition of mandatory training for implant surgeons, and the submission of an acceptable protocol for a postapproval study. The applicant provided satisfactory revisions to the labeling and a postapproval protocol.

### A. Labeling

CDRH agreed with the Panel that it is necessary for the labeling to address the safety issue regarding case fractures in the pediatric population. Anatomical and behavioral factors unique to the pediatric population create a specific risk profile for the CLARION cochlear implant in children. CDRH seeks to inform parents of children who are candidates for a cochlear implant that they should judge the activity level of their children as a consideration in selecting the CLARION model 1.2 device. Advanced Bionics agreed to place this information in a boxed format in the Package Insert under the "Warnings" section. A similar statement will appear in the Information Guide for Parents and Children". The applicant had also revised the labeling to include the most recent adverse events and clinical study results.

### B. Training for Surgeons and Audiologists

CDRH agreed with the Panel's recommendation that implantation of the CLARION model 1.2 device in the pediatric population should be restricted to physicians who have successfully completed an appropriate training course on specific procedures for implanting the device in children. CDRH concludes that mandatory training be implemented in accordance with section 515(d) (1) (B) (ii) of the Federal Food, Drug, and Cosmetic Act. The training proposal submitted by Advanced Bionics is acceptable. The company has agreed to provide an appropriate training program for pediatric implant surgeons with updates to the training course as necessary over time.

Although the Panel recommended mandatory training for the audiologist, CDRH has concluded that mandatory training should not be required. CDRH has not previously required training of audiologists who program cochlear implants, although such training has been strongly recommended. Further, there were no reports of adverse events caused by errors in programming technique. Therefore, the labeling will indicate that training is strongly recommended and that optimal results with the implant will not be obtained if the audiologist has not received training in the use of programming software, and state-of-the-art hearing aid fitting techniques and current pediatric evaluation practices.

C. **Postapproval Study**

CDRH concurred with the Panel's recommendation for a postapproval study to monitor the long-term safety and effectiveness of the CLARION. CDRH has concluded that an initial study of three years duration will be adequate to assess safety concerns and audiological performance. The need to continue the study for two additional years will be determined after a review of the three-year results submitted by the applicant.

CDRH understands the difficulty in obtaining long-term follow-up data from a large group of patients and has accepted Advanced Bionic's proposal to follow only the 73 patients from the PMA study whose 6-month effectiveness data was used to determine the clinical study effectiveness results. The 73 patients will be followed for electrical threshold, dynamic range, electrode impedance measurements, and a subset of the effectiveness measures used during the clinical trial. Advanced Bionics will also submit all device failure reports for the current and future CLARION pediatric population for the duration of the postapproval study.

CDRH concurred with the Panel's recommendation for a postapproval study to assess language development in children. The study will consist of 20 to 30 children of the 73 patients who have been followed in a longitudinal program of language development. A complete protocol, including preoperative and postoperative evaluations and data analysis methods will be submitted to CDRH within three months from the postapproval study.

The postapproval study will extend to March 1999, three years from the last implantation date among the 73 patients. At the end of the three-year period, an evaluation of the results will determine if a continuation of the study is needed.

FDA issued an approval order on June 26, 1997. The applicant's manufacturing facility was inspected on March 17-24, 1997, and was found to be in compliance with the device Good Manufacturing Practice Regulations.

## XII APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.

**PROPOSED LABELING (Revision Date: 06/25/97)**
**PACKAGE INSERT**
**CLARION® MULTI-STRATEGY™ COCHLEAR IMPLANT**

CLARION is a cochlear implant designed to provide useful hearing and consists of both implanted and external components. The internal components are surgically implanted under the skin behind the ear, and the external components, usually worn on the belt, include the speech processor, headpiece and cable. CLARION converts sounds in the environment into electrical code and transmits this code to the auditory nerve, and on to the brain where it is interpreted as sound.

**INDICATIONS:** The CLARION® Multi-Strategy™ Cochlear Implant, hereinafter referred to as CLARION, is intended to restore a level of auditory sensation to individuals with profound sensorineural deafness via electrical stimulation of the auditory nerve.

**Adults:**

- 18 years of age or older
- Profound, bilateral sensorineural deafness (≥90 dB)
- Postlingually deafened
- Lack of benefit from appropriately fitted hearing aids. In adults, lack of benefit with hearing aids is defined as scoring 20% or less on tests of open-set sentence recognition (CID Sentences).

**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
- 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% 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.

**CONTRAINDICATIONS:** Deafness due to lesions of the acoustic nerve or central auditory pathway; Active external or middle ear infections; Cochlear ossification that prevents electrode insertion; Absence of cochlear development; Tympanic membrane perforations associated with recurrent middle ear infections.

**WARNINGS:**

- **Impact** to the implant site can damage the implant resulting in device failure. There have been instances of CLARION device failure as a result of a child hitting his/her head at the site of the implanted device. None of these reported incidents have resulted in a concussion or fracture of the skull. In all cases, the failed device was explanted and a new device reimplanted with no further complications.

  When engaging in physical activities that include the possibility of trauma or impact, extra precautions should be taken, such as using a protective helmet, to reduce the risk of damage to the implant. Contact sports in which blows to the head or impact at the implant site are likely to occur should be avoided.

  Parents considering a cochlear implant for their child should evaluate their child's activity level before selecting a device.

- **Insertion of an intracochlear electrode** will result in the loss of any residual hearing in the implanted ear.

- **Electrode displacement** can occur if the electrode is not inserted properly. Surgeons should be proficient in the use of the electrode insertion tool.

- **Failure to follow the recommended surgical procedure for placement and stabilization of the CLARION implant increases the risk of device migration or extrusion and damage due to impact trauma, including breakage of the electrode lead wires. Creating a recessed bed or well for the implant and securely stabilizing the device in place with sutures are critical elements of the recommended surgical procedure.**

- **Extreme direct pressure** on the implanted device, up, down, left or right may cause the implant to move and possibly dislodge the electrode array.

- The long term effects of **chronic electrical stimulation** are unknown. Such effects may include new bone growth in the cochlea or deterioration of the auditory nerves. These effects may preclude replacement of the electrode array or lead to deterioration of the cochlear response.

- Exposure of the cochlear implant to a **Magnetic Resonance Imaging (MRI)** device may cause deleterious effects to the implant and to the patient. Individuals with a CLARION cochlear implant cannot undergo an MRI procedure or be in the same room with an MRI system, regardless of whether the system is in operation or not. The inability to undergo an MRI procedure prevents access to an important diagnostic modality.

- **Electrosurgical instruments** must not be used within the vicinity of the implant or electrode. Electrosurgical instruments are capable of producing radio frequency voltages of such magnitude that a direct coupling can effectively exist between the cautery tip and the electrode. Induced currents could cause damage to the cochlear tissues or permanent damage to the implant.

- **Diathermy** must never be applied over the implant or electrode. High currents induced into the electrode can cause tissue damage to the cochlea or permanent damage to the implant.

- **Electroconvulsive therapy** must never be used on a cochlear implant patient. Electroconvulsive therapy may cause tissue damage to the cochlea or permanent damage to the implant.

- **Ionizing Radiation Therapy** cannot be used directly over the implant as it may damage the device.

- The effects of **cobalt treatment and linear acceleration** techniques on the implant are unknown.

**PRECAUTIONS:**

- **Electrostatic Discharge (ESD):** Static electricity has the potential of damaging the electrical components of a cochlear implant system. Care should be taken to avoid situations in which static electricity is commonly created, such as when pulling on and off clothes or walking across a wool rug. If static electricity is present, patients should touch something conductive (e.g., a metal object) prior to handling the external equipment or before their cochlear implant system contacts another person or object. Children should remove their headpiece and speech processor before engaging in activities that commonly create static electricity, such as playing on plastic play equipment.

- **Digital Cellular Phones:** Using or being in close vicinity to someone using some digital cellular phones may cause interference with your CLARION system. If such interference occurs, patients can turn off their speech processor or move a greater distance from the source of the problem. Before purchasing a digital cellular phone, patients should evaluate whether or not it causes interference with their CLARION system. No such interference has been noted with cellular phones using analog technology.

- **Ingestion of Small Parts:** The external components of the implant system contain small parts which may be harmful if swallowed.

- **Airport/Security Metal Detectors:** Individuals with a cochlear implant should be advised that passing through security metal detectors may activate the detector alarm; thus, it is advised that patients carry their "Patient Emergency Identification Card" with them at all times.

- **Range of Benefits:** Cochlear implants do not restore normal hearing and benefits vary from one individual to another. Benefits range from the recognition of speech and sounds at comfortable listening levels to speech understanding without lipreading. There appears to be little correlation between the degree of benefit obtained from an implant and the cause of deafness. There are no definitive tests which can be administered prior to implantation that estimate the degree of benefit an individual may receive. Not all adult patients will achieve at least 20% on tests of open-set sentence recognition without lipreading (i.e., CID Sentences) with the implant. Not all children will achieve greater than 0% on open-set word recognition (PB-K Word List) with the implant. (Refer to Clinical Study Results.)

- **Use of Speech Processor:** Implant recipients should only use the speech processor that has been specifically programmed for them by their clinician. Use of a different speech processor may be ineffective in providing sound information and may cause physical discomfort from overstimulation.

**CLINICAL CONSIDERATIONS:** Optimized hearing aid fitting and evaluation procedures are critical to the selection of suitable cochlear implant candidates. In order to ensure selection of appropriate candidates, audiologists must be highly skilled in administering test procedures used to determine cochlear implant candidacy. They should be knowledgeable about and utilize clinically accepted state-of-the-art hearing aid technology, diagnostic instruments and fitting procedures.

When a patient is determined to be eligible for CLARION, the ear for implantation is selected. The following hierarchy of considerations is recommended:

- **Cochlear patency and the scala tympani.** The ear with the least cochlear ossification and the most normal appearing scala tympani, according to radiographic evidence is given primary consideration and takes precedence over other factors.

- **Residual hearing.** The ear with the poorest functional hearing is selected for implantation.

- **Duration of hearing loss.** If one ear has sustained deafness for a longer period of time than the other ear, the ear with the most recent onset of deafness is selected.

- **Age of onset.** In adults, ears which have experienced prelingual or congenital loss should not be implanted. Adult patients should have a history of auditory perception and speech and language development. In children, prelingual or congenital loss is not a determining factor.

- **Patient preference.** In adults, if both ears are equivalent in all regards, the patient's preference should be the determining factor in selecting the ear for implantation.

**ADVERSE EVENTS:** The following information considers adverse events for both the adult and pediatric study populations.

**Adult Safety Data** are based on a total of 273 patients who were implanted during the adult clinical study (148 U.S. patients and 125 international patients) of CLARION. The following adverse events occurred:

Device Failures

- Two patients experienced electronic device failures and required surgery to replace the device.

Medical/Surgical Complications

- **For all patients, insertion of the intracochlear electrode array resulted in the loss of residual hearing in the ear that was implanted.**

- Five patients experienced device migration, one patient experienced device extrusion, and two patients experienced device exposure. These problems were due to improper surgical placement of the implant.

- Three patients experienced electrode displacement (one case of full displacement and two cases of partial displacement) due to improper use of the electrode insertion tool.

- One patient experienced an inability to achieve magnetic adherence between the headpiece and the implant which was resolved by a surgical thinning of the flap over the implant.

- One patient experienced skin irritation over the implant which resolved without treatment or surgical intervention.

- Ninety-eight patients were evaluated for preoperative and postoperative vestibular symptoms. Follow-up time varied from six to 24 months. Of the 83 patients who reported no preoperative vestibular symptoms, 26 patients reported mild, fluctuating dizziness postoperatively. None of the cases of postoperative dizziness required medical intervention.

- Forty-six patients participated in filling out a tinnitus questionnaire at the 12 month postoperative follow-up. Four patients who reported experiencing no tinnitus prior to surgery reported tinnitus postoperatively with the implant turned both on and off. Twenty-two patients who reported experiencing tinnitus prior to surgery reported no tinnitus postoperatively with the implant turned on.

Other Complications

- Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming the Speech Processor.

**Pediatric Safety Data** are based on a total of 510 children (189 representing a version of the device that is no longer available and 321 representing the current manufacturing process) as of May 15, 1997, who were implanted during the pediatric clinical study (242 U.S. and 268 international) of CLARION. The following adverse events occurred:

**Device Failures**

- Three patients experienced a device failure as a result of damage to the ceramic case. These failures occurred among 321 implantations of which 82 have been implanted for over one year. These failures were the result of a direct impact to the implanted device. There was no effect associated with the aging of the ceramic material or the duration of implantation. All three patients have been explanted and reimplanted with a new device. Two additional patients experienced device failure due to causes yet to be determined and will require surgery to replace the device.

- One patient experienced electronic device failure and required surgery to replace the device.

- One patient experienced device failure due to an undetermined cause and required surgery to replace the device.

- Seven patients experienced device failure as a result of damage to the electrode array and required surgery to replace the device. These failures were associated with surgical placement of the device which deviated from the recommended surgical technique.

**Medical/Surgical Complications**

- **Insertion of an intracochlear electrode array is known to result in the loss of residual hearing in the ear that is implanted.**

- One patient developed fluid under the wound as a result of otitis media which was resolved through I.V. antibiotics and surgical intervention to debride, irrigate and drain the implant site.

- One patient developed an infection at the implant site as a result of incorrect placement of the electrode array. The device was explanted.

- One patient experienced facial nerve paralysis following implantation. Exploratory surgery revealed that the electrode lead was pressing on the VIIth nerve. Re-positioning of the electrode lead relieved the pressure on the nerve and substantial improvement has occurred.

- One patient experienced facial nerve paralysis due to an anomalous positioning of the VIIth nerve.

- One patient experienced facial nerve weakness attributed to post-surgical edema. The condition resolved spontaneously without treatment or surgical intervention.

- Three patients experienced irritation over the implant site. The conditions resolved spontaneously without treatment or surgical intervention.

- Two patients reported pain in the area of the implant site. The conditions resolved spontaneously without treatment or surgical intervention.

- Three patients experienced middle ear infection postoperatively and one patient experienced middle ear involvement at the time of implantation. The conditions resolved spontaneously or with minimum treatment, without surgical intervention.

- Three patients experienced fever following surgery. The conditions resolved spontaneously or with minimum treatment, without surgical intervention.

**Other Complications**

- One patient experienced facial nerve stimulation during programming. The condition resolved by reprogramming the Speech Processor.

**POSSIBLE ADVERSE EVENTS:** Although there were no reports during the adult and pediatric clinical study of the following adverse events, these additional events are known to be possible adverse events associated with cochlear implantation.

- Implant patients incur the normal risks of surgery and general anesthesia.

- Major ear surgery may result in numbness, swelling or discomfort about the ear, disturbance of taste or balance, or neck pain. If these occur, they are usually temporary and subside within a few weeks of surgery.

- Rarely, cochlear implantation may cause a leak of the inner ear fluid, which may result in meningitis.

**CLINICAL STUDY RESULTS - ADULTS:** Clinical results were achieved in a study of postlingually deafened (≥90 dB) adults who were consecutively implanted with CLARION. Results are reported for the number and proportion of patients demonstrating statistically significant improvement and achieving a particular level of performance. Improvement results are based on comparisons to pre-implant data in the best aided condition utilizing critical improvement scores. The study subjects were tested in quiet at normal conversational levels (50 - 55 dB HL) at six months of device usage.

- Sixty-eight subjects (100%) detected speech and sounds at comfortable listening levels. (68 subjects tested)

- Fifteen subjects (28%) demonstrated improvement in the recognition of familiar warning signals compared to aided pre-implant performance. Preoperatively with hearing aids, 23 subjects (43%) identified half or more of familiar warning signals. Postoperatively with the implant, 47 subjects (89%) identified half or more of familiar warning signals. (53 subjects tested)

- Fifty-eight subjects (87%) improved their communication ability when the device was used in conjunction with lipreading compared to aided pre-implant performance. Fifty-six subjects (84%) achieved scores over 50% on sentences with lipreading. Forty-nine subjects (73%) achieved scores over 75% on sentences with lipreading. Thirty-four subjects (51%) achieved scores over 90% on sentences with lipreading.[1] (67 subjects tested)

  [1]CUNY Sentences, representing standard everyday speech, presented via laser disk and requiring exact repetition.

- Fifty subjects (74%) demonstrated improvement in open-set sentence recognition without lipreading compared to aided pre-implant performance. Fifty-one subjects (75%) achieved scores over 20% on sentences without lipreading. Thirty-five subjects (51%) achieved scores over 80% on sentences without lipreading. Seventeen subjects (25%) achieved scores over 95% on sentences without lipreading. Seventeen subjects (25%) scored less than 20% on sentences without lipreading.[2] (68 subjects tested)

  [2]CID Sentences, representing standard everyday speech, presented via monitored audio tape recordings and requiring recognition of key words.

- Forty-seven subjects (69%) demonstrated improvement in open-set monosyllabic word recognition without lipreading compared to aided pre-implant performance. Thirty-four subjects (50%) achieved scores of 30% or greater on monosyllabic words without lipreading. Twenty-three subjects (34%) achieved scores over 45% on monosyllabic words without lipreading. Eighteen subjects (26%) achieved scores of 50% or greater on monosyllabic words without lipreading.[3] (68 subjects tested)

  [3]NU-6 Words, representing single syllable words, presented via monitored audio tape recordings and requiring exact repetition.

- Forty-three subjects (64%) demonstrated improvement in open-set sentence recognition, over the telephone compared to aided pre-implant performance. Thirty-six subjects (54%) achieved scores over 65% on sentences heard over the telephone. Twenty-seven subjects (40%) achieved scores over 80% on sentences heard over the telephone. Eighteen subjects (27%) achieved scores over 95% on sentences heard over the telephone.[4] (67 subjects tested)

  [4]Overlearned Sentences, representing previously unknown, familiar phrases, presented over the telephone and requiring recognition of key words.

- Fifty-one subjects (75%) self-assessed their ability to communicate without lipreading as improved compared to aided pre-implant performance. Fifty-eight subjects (85%) self-assessed their ability to communicate with lipreading as improved compared to aided pre-implant performance. (68 subjects tested)

**CLINICAL STUDY RESULTS - CHILDREN:** Clinical results were achieved in a study of 73 children with profound sensorineural hearing loss (≥90 dB) who were consecutively implanted with CLARION. Results are reported for the number and proportion of children demonstrating statistically significant improvement and achieving a particular level of performance. Improvement results are based on comparisons to pre-implant data in the best aided condition utilizing critical improvement scores. Post-implant testing with CLARION was conducted using unmonitored live voice presentation in the sound only condition (without lipreading) at six months of device usage.

Children were grouped into younger (n=45) and older (n=28) categories according to whether the child was administered Level 1 or Level 2 test measures. Level 1 and Level 2 tests differ in degree of difficulty. Level 1 testing was administered to children three years of age and younger. Level 2 testing was administered to children seven years of age and older. Children aged four, five and six were administered a developmental test to assess basic language skills. Based on the results of this testing, children aged four, five and six were administered either Level 1 or Level 2 test measures.

**Subjective Test Measures**

- Preoperatively, with hearing aids, 11% of the children frequently or always responded to their name in quiet. Postoperatively, with CLARION, 90% of the children frequently or always responded to their name in quiet.[5] (73 subjects tested)

- Preoperatively, with hearing aids, 3% of the children frequently or always responded to their name in noise. Postoperatively, with CLARION, 52% of the children frequently or always responded to their name in noise.[5] (73 subjects tested)

- Preoperatively, with hearing aids, 7% of the children frequently or always alerted to environmental sounds. Postoperatively, with CLARION, 78% of the children frequently or always alerted to environmental sounds.[5] (73 subjects tested)

- Preoperatively, with hearing aids, 10% of the children frequently or always recognized sounds in the home or school environment. Postoperatively, with CLARION, 62% of the children frequently or always recognized sounds in the home or school environment.[5] (73 subjects tested)

- Preoperatively, with hearing aids, 10% of the children frequently or always were able to discriminate between the voices of two speakers. Postoperatively, with CLARION, 55% of the children frequently or always were able to discriminate between the voices of two speakers.[5] (73 subjects tested)

[5]Meaningful Auditory Integration Scale (MAIS) - a five-point parent report scale, objectively scored, used to assess the frequency of behaviors in response to sound in everyday situations. (Levels 1 and 2)

- Preoperatively, with hearing aids, 29% of the children frequently or always varied the rhythm of their vocalizations. Postoperatively, with CLARION, 52% of the children frequently or always varied the rhythm of their vocalizations.[6] (73 subjects tested)

- Preoperatively, with hearing aids, 36% of the children frequently or always were willing to communicate about a familiar topic using speech only. Postoperatively, with CLARION, 62% of the children frequently or always were willing to communicate about a familiar topic using speech only.[6] (73 subjects tested)

- Preoperatively, with hearing aids, 32% of the children frequently or always were willing to communicate about an unfamiliar topic using speech only. Postoperatively, with CLARION, 55% of the children frequently or always were willing to communicate about an unfamiliar topic using speech only.[6] (73 subjects tested)

[6]Meaningful Use of Speech Scale (MUSS) - a five-point parent report scale, objectively scored, used to assess the frequency of speech production in everyday situations. (Levels 1 and 2)

### Objective Test Measures

**Preoperatively with hearing aids, children demonstrated a range of performance on objective test measures.**

- Fifty-one percent (51%) of younger children demonstrated improvement in the identification of single syllable words when presented with a choice of four objects compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Eight children (18%) identified 100% of the words. Nineteen children (42%) identified 75% or more of the words. Twenty-three children (51%) identified 50% or more of the words. Twenty children (44%) were assigned a chance score of 25%.[7]

[7]Early Speech Perception Test (ESP) Low Verbal Version - a test used to evaluate a child's identification of single syllable (monosyllabic) words when presented with a choice of four objects. If a child is unable to perform the test, a chance score of 25% is assigned. (Level 1)

- Seventy-nine percent (79%) of older children demonstrated improvement in the identification of single syllable words when presented with a list of twelve words compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Six children (21%) identified 100% of the words. Thirteen children (46%) identified 92% or more of the words. Twenty-two children (79%) identified 54% or more of the words. Twenty-four children (86%) identified 20% or more of the words. Four children (14%) identified less than 20% of the words.[8]

[8]Early Speech Perception Test (ESP) Standard Version - a test used to evaluate a child's identification of single syllable (monosyllabic) words when presented with a list of twelve words. (Level 2)

- Forty-two percent (42%) of younger children demonstrated improvement in the recognition of speech sounds (i.e., vowels and consonants) compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Seven children (16%) recognized 50% or more of the speech sounds. Twenty children (44%) recognized 20% or more of the speech sounds. Twenty-five children (56%) recognized less than 20% of the speech sounds.[9]

- Seventy-nine percent (79%) of older children demonstrated improvement in the recognition of speech sounds (i.e., vowels and consonants) compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Three children (11%) recognized 90% or more of the speech sounds. Nine children (32%) recognized 75% or more of the speech sounds. Eighteen children (64%) recognized 51% or more of the speech sounds. Seven children (25%) recognized less than 20% of the speech sounds.[9]

[9]Phonetically Balanced Kindergarten Test - Phonemes (PB-K) - a test used to evaluate a child's ability to recognize individual speech sounds (i.e., vowels and consonants). (Levels 1 and 2)

- Thirty-one percent (31%) of younger children demonstrated improvement in the recognition of sentences compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Six children (13%) recognized 70% or more of the sentences. Ten children (22%) recognized 50% or more of the sentences. Fifteen children (33%) recognized 20% or more of the sentences. Thirty children (67%) recognized less than 20% of the sentences.[10]

[10]Mr. Potato Head - a test used to evaluate a child's recognition of familiar phrases. (Level 1)

- Seventy-nine percent (79%) of older children demonstrated improvement in the recognition of sentences compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Six children (21%) recognized 100% of the sentences. Nine children (32%) recognized 90% or more of the sentences. Fifteen children (54%) recognized 60% or more of the sentences. Twenty-four children (86%) recognized 20% or more of the sentences. Four children (14%) recognized less than 20% of the sentences.[11]

[11]Common Phrases - a test used to evaluate a child's recognition of familiar phrases encountered in everyday situations. (Level 2)

- Thirty-three percent (33%) of younger children demonstrated improvement in the recognition of words compared to pre-implant performance with hearing aids. The patients in the study sample (n=45) demonstrated a range of performance postoperatively. Five children (11%) recognized 80% or more of the words. Thirteen children (29%) recognized 50% or more of the words. Sixteen children (36%) recognized 20% or more of the words. Twenty-nine children (64%) recognized less than 20% of the words. [12]

[12]Mr. Potato Head - a test used to evaluate a child's recognition of words in familiar phrases. (Level 1)

- Sixty-eight percent (68%) of older children demonstrated improvement in the recognition of single syllable words compared to pre-implant performance with hearing aids. The patients in the study sample (n=28) demonstrated a range of performance postoperatively. Eight children (29%) recognized 52% or more of the words. Sixteen children (57%) recognized 20% or more of the words. Twelve children (43%) recognized less than 20% of the words. [13]

[13]Phonetically Balanced Kindergarten Test - Words (PB-K) - a test used to evaluate a child's ability to recognize single syllable (monosyllabic) words. (Level 2)

**TELEMETRY:** The CLARION system incorporates bi-directional telemetry that can be used to verify system functionality. Due to the presence of air bubbles in saline or in the cochlear fluids, pre- and intraoperative testing via the CLARION's telemetry system may prevent verification that all 16 electrodes are functional prior to or at the time of surgery.

**STORAGE:** CLARION should be stored at temperatures in the range of 0° to 50° Centigrade (32° to 122° Fahrenheit).

**HANDLING:** Severe impact could damage the storage pack and rupture the sterile packaging. An impact with a force in excess of 85 pounds could fracture the ceramic case. Therefore, it is good practice to handle the package with the care appropriate to any implantable medical device.

**SHELF LIFE:** A "Use Before" date is located on the device packaging. This date is two years from the date of sterilization. The cochlear implant itself is not subject to aging.

**STERILIZATION:** CLARION is supplied in ethylene oxide sterile packaging with indicators of sterilization. Sterile packs should be carefully inspected to confirm that they have not been ruptured. Sterility cannot be guaranteed if the sterile package is damaged or opened.

**INFORMATION FOR USE AND REQUIRED TRAINING:** A *Surgeon's Manual* and a video describing the surgical procedure and insertion of the electrode are provided to all physicians prior to implantation. Physicians must be well versed in mastoid surgery and the facial recess approach to the round window. Advanced Bionics conducts periodic training courses on the recommended surgical procedure to implant CLARION and strongly recommends that surgeons who implant adults receive training.

All physicians implanting CLARION in children must be trained in the implantation procedure for the CLARION cochlear implant. Failure to obtain the appropriate training will result in a higher incidence of surgical and medical complications.

Surgeons should work with an audiology professional who has been fully trained on the proper fitting and adjustment of the CLARION cochlear implant.

A *Device Fitting Manual* is provided to all clinical centers with the Clinician's Programming System. Audiologists must be highly skilled in administering test procedures used to determine cochlear implant candidacy. They should be knowledgeable about state-of-the-art hearing aid technology and fitting procedures. Additionally, at least one audiologist from a clinical center should be fully trained and qualified in the fitting of the CLARION cochlear implant in both adults and children. Advanced Bionics conducts periodic training courses for audiologists and strongly recommends that audiologists attend a training course. Failure to obtain the appropriate training will result in less than optimal patient performance.

A *Portable Cochlear Implant Tester* (PCIT) Manual is provided to all clinics in the PCIT Kit. This manual describes operation and use of the PCIT. Clinicians should be trained in the use of the PCIT.

Pamphlets entitled *Introduction to CLARION for Adults* and *Introduction to CLARION for Parents and Children* are available to individuals inquiring about a cochlear implant. These pamphlets are designed to assist in answering basic questions that a prospective patient may have and to serve as a tool for professionals in patient screening.

Manuals entitled *Information Guide for Adults*, *Information Guide for Parents and Children* and *CLARION User's Guide* are provided to the audiologist and should be given to all prospective candidates and CLARION recipients. The *User's Guide* describes how to use the external components of the CLARION system. The information guides provide detailed information about CLARION, indications for use, benefits, risks, and what is involved in patient selection, surgical and out-patient procedures.

**CAUTION:** Federal law restricts this device to sale, distribution and use by or on the order of a physician. For use in children, federal law restricts this device to sale, distribution and use by or on the order of a physician who is trained in the pediatric implantation procedures for the CLARION cochlear implant.

C919 6252-001 Rev A Pediatric PMA 6/97

# PROPOSED LABELING
# (REVISION DATE 6/24/97)
# CLARION® MULTI-STRATEGY™ COCHLEAR IMPLANT SYSTEM

# INFORMATION GUIDE FOR PARENTS & CHILDREN

**CAUTION:** **Federal law restricts this device to sale, distribution and use by or on the order of a physician. For use in children, federal law restricts this device to sale, distribution and use by or on the order of a physician who is trained in the pediatric implantation procedures for the CLARION cochlear implant**

**Authorized to affix the CE mark in 1993.**

**Advanced Bionics® Corporation**
**12740 San Fernando Road**
**Sylmar, CA 91342-3728**

This device is protected under one or more of the following U.S. Patents: 3,751,605, 3,752,939, 4,400,590, 4,405,831, 4,495,917, 4,686,765, 4,721,551, 4,819,647, 4,837,049, 4,969,468, 4,991,582, 4,931,795, 4,990,845, RE. 33,170. Other U.S. and/or foreign patents may be pending.

June 24, 1997

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This guide is for parents who are considering a CLARION® Multi-Strategy™ Cochlear Implant for their child. It is designed to serve as a reference guide and instructional aid for learning about CLARION. While intended to answer basic questions, it is not a substitute for evaluation, training and counseling by a cochlear implant team. The cochlear implant team is the best source of information and can provide answers to any additional questions that you may have about cochlear implants. Additionally, the cochlear implant team can provide information to you about alternative treatments and options for your child.

# I. INTRODUCTION TO COCHLEAR IMPLANTS

A cochlear implant is a small electronic device designed to provide useful hearing to children who are profoundly hearing impaired and unable to achieve speech understanding with hearing aids. Hearing aids (and other types of assistive listening devices) make sounds louder and deliver the amplified sounds to the ear. However, for most individuals with a profound hearing loss, even the most powerful hearing aids may provide little or no benefit.

A profoundly deaf ear is typically one in which the majority of sensory receptors of the inner ear, called hair cells, are damaged or absent. Making sounds louder or increasing the level of amplification does not enable such an ear to process sound. Cochlear implants bypass the damaged hair cells and stimulate the hearing nerves, allowing individuals who are profoundly or totally deaf to receive sound.

Cochlear implant technology was first researched and developed in the 1960s and 1970s. Since that time, cochlear implant systems have continued to improve from the first single-channel systems to the more recent multichannel devices. Today, advances in computer hardware and software and sound processing technology have produced implant systems that provide better sound than ever before.

Single-channel devices were introduced in the 1970s. These early single electrode devices sent coded information to only one electrode site in the inner ear. These devices provided patients with speech and sound awareness and enhanced lipreading. Generally, speech understanding without lipreading was not achieved.

The introduction of multichannel devices in the 1980s represented a major advance in technology. Multichannel devices stimulate nerve fibers at multiple locations along the length of the cochlea and, thus, provide greater pitch discrimination. Stimulating nerve fibers at multiple locations is important because each nerve fiber in the inner ear is "tuned" to a different pitch depending on its location. Hearing nerves are organized so that high frequencies are picked up at the base of the cochlea while low frequencies are picked up at the center or apex. This arrangement is referred to as the "tonotopic" organization of the ear. With the introduction of multichannel systems, some cochlear implant recipients were able to understand speech without lipreading.

The latest advance in cochlear implant technology has been the development of multichannel systems that provide users with access to more than one speech processing strategy. Speech processing is the method by which sound is converted or "processed" into electrical signals that can be sent to the brain to be interpreted as sound. The ability of a cochlear implant system to allow patients to experience and use more than one speech processing strategy is referred to as multi-strategy.

# IV. FEATURES OF CLARION

## A. Flexibility

Flexibility in a cochlear implant system is needed because cochlear implant candidates have unique and diverse auditory needs. Individual patient characteristics exert a strong influence on performance with a cochlear implant, and despite years of research, there are no diagnostic tests to determine how well a patient will perform prior to implantation. Therefore, flexibility is built into the CLARION system through multiple stimulating methods, multiple channels, multiple output circuits, multiple strategies and multiple programs to help match each user's needs.

### 1. Multiple Stimulating Methods

There are different methods of providing stimulation to the implanted electrodes when using the CLARION system. Electrical impulses can be delivered simultaneously and sequentially. CLARION is the only implant systems capable of delivering stimulation using both of these methods.

### 2. Multiple Strategies

Because CLARION is the only cochlear implant system capable of delivering stimulation both simultaneously and sequentially, it can offer multiple speech processing strategies. Speech processing strategies are methods of converting or "processing" incoming sound into electrical signals. Different speech processing strategies convert sound in fundamentally different ways and are analogous to different computer software packages. Today, CLARION can be programmed with the following strategies:

- Continuous Interleaved Sampler (CIS), which converts sound into digital pulses and delivers stimulation to the electrodes sequentially.
- Simultaneous Analog Stimulation (SAS), which converts sound into analog waveforms and delivers stimulation to the electrodes simultaneously.

In the clinical study of CLARION with children, all children were programmed with the CIS strategy.

### 3. Multiple Channels

CLARION is a multichannel cochlear implant that stimulates selected nerve fibers at multiple locations along the length of the cochlea. This design provides for greater pitch discrimination than previous single channel cochlear implants. In total, CLARION has eight independent, programmable channels and sixteen electrode contacts.

### 4. Multiple Output Circuits

To power these multiple channels, CLARION utilizes eight independent output circuits. Other multichannel cochlear implant systems have only one output circuit, or driver, and are, therefore, limited to generating sequential stimulation and a single type of waveform. Because CLARION has eight independent output circuits, each channel can be individually programmed. CLARION is the only cochlear implant with this powerful design.

### 5. Multiple Programs

In addition to being able to utilize different speech processing strategies and stimulating methods, CLARION can store three user-defined programs, or maps, in one speech processor. Maps are subsets of speech processing strategies, and store different information, such as varying threshold or loudness levels. CLARION can store three maps in its speech processor, which enables users to switch between programs as the need arises in their listening environment.

**B. Speed**

Speech sounds fluctuate rapidly, with changes in the relative intensity of different frequencies of sound occurring in only a few milliseconds. Thus, it is important for a cochlear implant to deliver stimulation at a sufficiently fast rate.

Fast stimulation allows for detailed representation of speech sounds to be delivered to the hearing nerves. CLARION's powerful implant is capable of transmitting up to 104,000 pieces of information per second when using the SAS processing strategy, and 6,664 pulses per second when using the CIS processing strategy. CLARION delivers stimulation faster than any other cochlear implant commercially available in the United States.

**C. Safety**

CLARION incorporates many safety features. All cochlear implant systems send information from the external components to the implant, but CLARION also transmits information from the implant back out to the external components. Known as bi-directional telemetry, this safety feature continuously monitors the integrity of the implanted components and allows for device testing in the operating room and continuously thereafter. Bi-directional telemetry assures the patient, parent and physician that the implant components are functioning properly.

To prevent the passage of direct current (DC), which can cause damage to cochlear tissues and corrode electrodes, CLARION's implanted electronics include special capacitively coupled output circuits. Capacitors are attached to each electrode and ensure that current is charge-balanced.

Additionally, both CLARION's internal electronics and receiving coil are sealed within an alumina ceramic case to prevent breakage between the coil and electronic package.

**D. Leadership**

As a company which evolved from the world's second largest cardiac pacemaker manufacturer, and largest manufacturer of implantable and external insulin pumps, Advanced Bionics has a rich history in developing miniaturized, implantable medical devices. Advanced Bionics' first commercial product, CLARION, has introduced technological innovations that have significantly advanced the field of cochlear implants. CLARION was the first cochlear implant commercially available in the United States to feature:

- Multiple stimulating methods which provide patients with both simultaneous and sequential stimulation
- CIS processing strategy for sequential stimulation
- SAS processing strategy for simultaneous stimulation
- Eight independent output circuits capable of generating different waveforms on any of eight channels
- Processing speed of 104,000 pieces of information per second to represent rapid fluctuations in sound
- Fully upgradeable software for easy programming
- Multiple programs in one speech processor for various listening environments
- Bi-directional telemetry for continuous device diagnostics
- Capacitively coupled circuits to prevent leakage of damaging direct current
- Antenna enclosed in an alumina ceramic case
- Spiral electrode array to conform to the natural shape of the cochlea
- Integrated single-unit headpiece for aesthetic appeal

Advanced Bionics is committed to continuing the advancement of cochlear implant technology through aggressive research and development.

## V. CANDIDACY REQUIREMENTS FOR CHILDREN

Eligibility for the CLARION is determined by the implant center after the child has completed a series of evaluations. The general criteria for children are:

- **Age:** 2 through 17 years of age. The cochlea is adult size at birth, and by 2 years, skull growth is complete. In special circumstances, children as young as 18 months may be implanted if they have had meningitis and x-rays show evidence of ossification, or bone growth in the cochlea.

- **Degree of Hearing Loss:** Profound, sensorineural hearing loss of 90 dB or greater in both ears.

- **Hearing Aid Use:** In general, it is recommended that appropriately fitted hearing aids be used for at least 6 months before determining implant candidacy. In some cases of total hearing loss from meningitis, a shorter hearing aid trial might be recommended.

- **Lack of Benefit from High Powered Hearing Aids:** In younger children, lack of benefit from 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 (MAIS). In older children, lack of benefit is defined as scoring 0% on open-set word recognition (PB-K Word Test) 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.

- **Rehabilitative or Educational Setting:** Children should be in a rehabilitative or edcuaional setting where the development of listening and speaking skills is emphasized.

- **Family Support:** Children should be in a positive family environment where use of their device, listening and speaking are encouraged.

## VI. PRE-IMPLANT EVALUATION

In order to determine whether a child is a candidate for CLARION, the following evaluations should be performed:

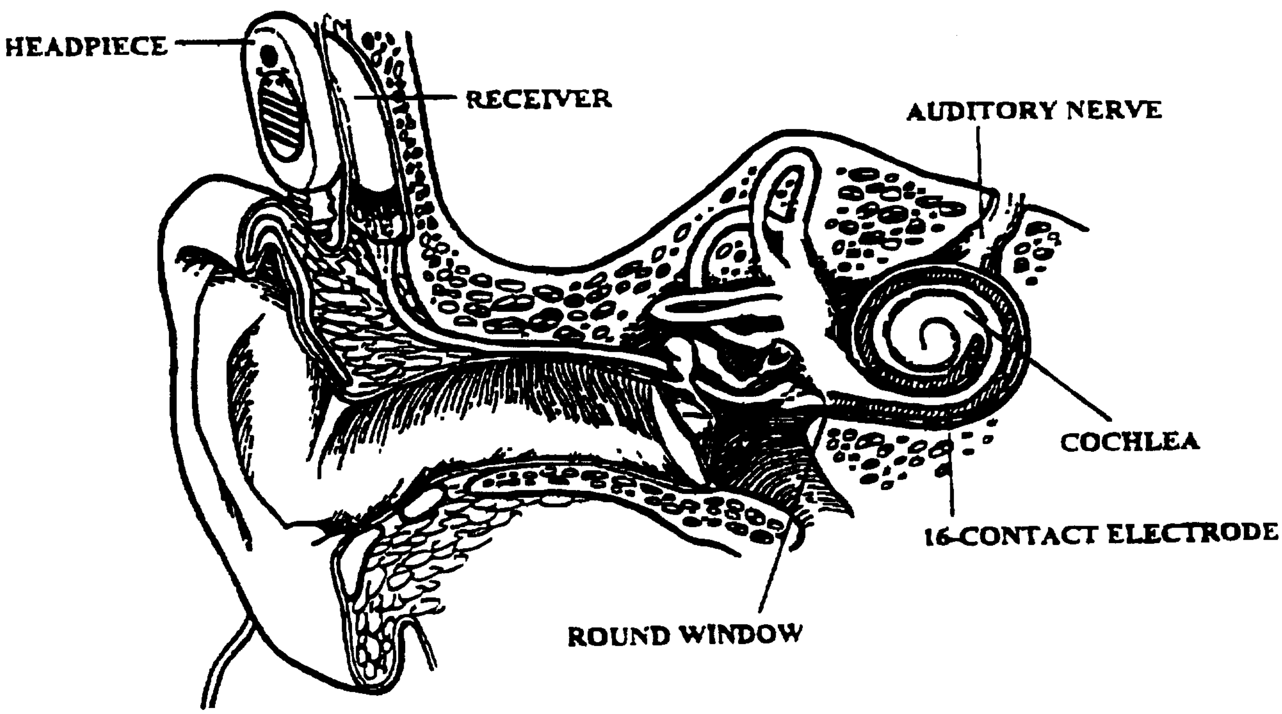
- An audiological evaluation to confirm the presence of a profound sensorineural hearing loss in both ears. This will also include an evaluation of the child's ability to process various aspects of the speech signal when using hearing aids to determine if he/she has been using the appropriate ones. If the audiologist feels that the child might benefit from different hearing aids, it will be recommended that these hearing aids be used for a period of time.

- Various medical tests such as an ear examination will be conducted to verify that there are no ear infections that might prevent (or delay) implantation. X-rays of the inner ear will reveal any bony growth (ossification) which might prevent implantation or permit only a partial insertion of the electrode array.

- Extensive counseling will be provided by the implant team with respect to the benefits and risks of cochlear implants. This will include a discussion of the medical and surgical risks, the range of benefits that might be expected, and the commitment required for implant fitting, evaluations and training.

## VII. SURGICAL PROCEDURE

The purpose of the surgical procedure is to implant the internal components of the system, consisting of the electronic receiver and the electrode array. The receiver is placed under the skin and behind the ear on the mastoid bone. The electrode array is inserted into the cochlea through the round window, for a distance of about 24 millimeters or approximately one and a half turns of the cochlea. The figure below shows an ear with the implanted components in place.




The surgery is done under general anesthesia and generally takes between one and three hours. Immediately before surgery, the small area behind and above the ear to be implanted is shaved to reduce the possibility of infection near the implant site. The hair grows back naturally over this area.

The procedure begins with an incision behind and above the ear that allows access to the cochlea and mastoid area. The incision must be sufficiently large so that the receiver and electrode array can be placed without any portion touching the line of incision. This reduces the possibility of infection. After the appropriate preparations, the electrode array is carefully inserted in the cochlea, the receiver is attached to the mastoid bone, and the incision is closed.

Patients are usually able to get out of bed and walk around their room the day of surgery and generally are discharged from the hospital on the first postoperative day. The sutures are removed approximately seven days after surgery.

Following release from the hospital, patients return home for a period of four to six weeks. This allows for a complete recovery period, although most children return to their normal activities within a week after surgery. The four to six week recovery period permits complete healing around the implant site prior to being fit with the external components of the system.

The possible adverse effects of cochlear implantation will be fully explained to you by the surgeon and audiologist. A detailed description of adverse effects can be found in the *Package Insert* located at the back of this guide.

## VIII. DEVICE FITTING

Because every child's hearing loss is different, CLARION is customized to each individual's needs. The process of customizing the device is referred to as device fitting.

A computerized program guides your child and audiologist through the fitting process. The fitting software used to program the CLARION takes into consideration the demands of fitting a young child. The audiologist and your child work together to find the processor settings that provide the best sound information to process speech. Because alternative techniques for programming the processor are available, the device fitting procedure varies in time for each individual. The audiologist may want to fit your child with different processing programs to find the one that yields the best results. The initial device fitting typically takes a few hours and may be done in one or more sessions.

### A. Initial Fitting Process

Initially, to create a program, sounds or tones are presented to each electrode or electrode pair (channel) until your child is able to detect the sound (threshold), and an appropriately loud (most comfortable) level is determined. Since your child may have limited experience with auditory stimulation and little or no understanding of the concept of loudness, this could be a time-consuming and frustrating process. To assist in creating the initial program, the CLARION fitting software has a unique interpolation feature that estimates the threshold and most comfortable levels from measured values on as few as one channel. Using this feature, a full program can be created for your child in less than half an hour. The fitting software also incorporates another feature that allows the audiologist to use meaningful live-voice speech in real time to make appropriate loudness level adjustments to your child's program.

In addition to the formal device fitting process, the audiologist will assess your child's performance through behavioral observation and comments. Based on test results, feedback and observations regarding what sounds best, the speech processor will be programmed with up to three programs. In this way, you and your child will be able to experiment and try different processing schemes in familiar environments.

CLARION gives the audiologist the opportunity to download three different speech processing programs into one speech processor. One program may be preferable for use in noise, such as the school setting, while another may be preferable in your home environment. The audiologist will work with your child to determine the speech strategy that is best for your child's needs.

In addition to device fitting, time will also be devoted to training you and your child on the use and care of the CLARION system. Discussions may include correct positioning of the headpiece, battery pack insertion, and use of the adjustable patient controls. Troubleshooting is also discussed. A complete discussion of how to use of the speech processor is contained in the *CLARION User's Guide*.

### B. Follow-up Visits

During the first several months of device use, your child should be seen on several occasions for readjustment of the speech strategies programmed into the speech processor. As your child becomes more sophisticated in his/her responses, the audiologist will continue to fine-tune the processor. Methods of promoting maximum use of the new sounds being heard as well as development of speech production and other communication skills may be explored.

Several months after the initial device fitting, the audiologist should administer an extensive audiological evaluation. These tests are used to measure the functional benefits gained from use of the device. The audiological assessment consists of tests that are similar to those given preoperatively.

## IX. POST-IMPLANT REHABILITATION AND SUPPORT

It is important that the child be in an appropriate educational setting and a positive family environment. Both of these factors can greatly affect the amount of benefit a child receives with the implant.

It is important that the family understand its role in the implant process. Following surgery, there will be follow-up medical visits, as well as appointments for the audiologist to program the speech processor. Generally, more visits are necessary with very young children because they have limited attention spans. Periodic audiologic evaluations will be necessary to evaluate the child's listening skills with the implant. These audiologic evaluations will be necessary as long as the child has an implant. It is essential that the family maintain appropriate expectations, help motivate their child to wear the device regularly and support their child's use of the implant.

Children with cochlear implants need special training to promote the development of their listening and speaking skills, just as do profoundly hearing-impaired children who use hearing aids. It is important that children with cochlear implants are in a rehabilitative/educational setting where such training is available and where emphasis is placed on the development of listening and speaking skills. There are a number of different types of training methods and school settings where such training is provided (e.g., oral/aural; auditory-verbal; cued speech; total communication). Clinical experience suggests that children who are not in an appropriate educational setting will not achieve optimal performance with their implant. The implant team can provide suggestions and assistance in working with the teachers and specialists in the child's educational setting.

## X. BENEFITS AND RISKS

CLARION offers a safe, reliable and effective alternative to profound hearing loss in children. Over the past few years, leading implant centers across America have participated in the clinical investigation of CLARION in children. Although individual patient benefits varied widely, the overall results of the clinical study showed significant improvement on all test measures after six months of device use.

Benefits achieved ranged from the detection of sounds to understanding speech without lipreading. Many children demonstrated significant gains in speech understanding. In general, the children who benefited the most were in good auditory training programs and have families who are firmly committed to the training process. Benefits are still emerging and children are continuing to show improvement.

There are no reliable methods to predict the degree of benefit that a child will receive from an implant. Each child has certain conditions which can influence his or her progress with the cochlear implant. It is important to keep in mind that *learning with an implant occurs over many years*, just as it does in children who use hearing aids. Some factors that have been found to influence performance are:

- **Amount of auditory nerve survival.** Children who have better nerve survival often perform better with an implant than those with poor nerve survival. Unfortunately, there are no tests that reliably determine the extent of nerve survival in an individual.

- **The presence of ossification (bony growth) in the cochlea.** Ossification can prevent a full insertion of the electrode array and reduce the number of channels of stimulation. A partial electrode insertion can adversely affect speech understanding with the implant.

- **Auditory memory.** Children who have some memory of spoken language before they lost their hearing show the most rapid improvements with multichannel implants. Children who are born deaf or acquire their deafness before they learn language will generally show slower rates of progress with an implant. Research has shown, however, that many children with early onset of deafness reach high levels of performance with their implants, just as do children who become deaf after they have learned some language.

A detailed discussion of clinical results, warnings and precautions can be found in the *Package Insert* located at the back of this guide.

## XI. FREQUENTLY ASKED QUESTIONS

The following section has been written to provide answers to some of the most commonly asked questions about cochlear implants.

***What will my child hear with a cochlear implant?***

Clinical study of CLARION has demonstrated that children can detect sounds at lower levels than deaf children with conventional hearing aids. The majority of children are able to respond to their name in quiet and in noise, alert to environmental sounds and recognize sounds in the home or school environment. The majority of children showed improvement in identifying single syllable words on basic speech perception tests. With training and experience, along with a nuturing home and school environment, most children can learn to tell differences between sounds and to understand varying degrees of speech.

***Will the implant help my child learn to talk?***

Although the primary role of a cochlear implant is to help children hear and understand speech, an implant also provides auditory information which may assist children learning to talk. The majority of children implanted with CLARION frequently or always use speech to communicate. Once children acquire the different sounds of speech, it may take several years to learn how to put the sounds together to produce words and sentences that listeners can understand. Some children develop better speech skills with their implant than others for reasons that are not clearly understood. Children who use implants may not develop speech that sounds completely "normal", just as an implant does not restore normal hearing.

***How soon should my child be implanted?***

The sooner your child is implanted, the sooner he/she will receive auditory stimulation and exposure to spoken language. Many children are implanted during early childhood (e.g. between ages 2 and 3) to take advantage of the early years of language development. Prelingually deafened children implanted at an older age have also demonstrated measureable benefit from CLARION. Research is still needed to clarify the effect that age at implantation has on implant performance.

***Does my child need special training with the implant?***

Children with implants benefit from auditory and speech training just as do children with hearing aids. Such training can be found in a variety of educational programs and settings: mainstreamed schools with resource support, self-contained classes in the public school setting, or schools for the deaf. Some children use oral communication, some use cued speech, while others use total communication. The most important factor is that the teachers have experience in providing auditory and speech training to children with profound hearing losses along with a general working knowledge of cochlear implants. This will help to maximize the benefit that the child may receive from the cochlear implant. Clinical experience suggests that children who are not in an appropriate educational setting will not achieve optimal performance with their implant.

*Is a cochlear implant safe?*

CLARION has been designed with many hardware and software features to ensure safety. However, long term safety data for individuals using CLARION is limited. Although there have been no obvious damaging effects from prolonged electrical stimulation, the long-term effects of electrical stimulation remain unknown.

***Are there any restrictions on physical activities with CLARION?***

The implanted device is capable of withstanding the effects of running, exercise and normal activity. Regardless of the activity, precautions must be taken in order to avoid a blow to the head which could result in damage to the implanted device resulting in device failure. There have been instances of CLARION device failure as a result of a child hitting his/her head at the site of the implanted device. None of these reported incidents have resulted in a concussion or fracture of the skull. In all cases, the failed device was explanted and a new device reimplanted with no further complications. When engaging in physical activities that include the possibility of trauma or impact, extra precautions should be taken, such as using a protective helmet, to reduce the risk of damage to the implant. Contact sports in which blows to the head or impact at the implant site are likely to occur should be avoided. Parents considering a cochlear implant for their child should evaluate their child's activity level before selecting a device.

The external components of the system should be protected from moisture and breakage. The speech processor and headpiece must be removed before bathing or swimming or when participating in an activity where the components could get wet. Additionally, children should remove their headpiece and speech processor before engaging in activities that commonly create static electricity, such as playing on plastic play equipment.

***How much does a cochlear implant cost?***

As with most medical prostheses, cochlear implants are expensive. The costs for evaluations, the device, surgery, hospitalization and fitting procedures are generally over $30,000. This amount varies from center to center depending on their charges and fees.

***Does insurance cover the cost for a cochlear implant?***

Many insurance carriers provide full or partial coverage for cochlear implants and the associated costs. The amount of coverage depends on the specific insurance carrier. The implant center submits the proper documentation to the insurance carrier for approval.

Additionally, reimbursement assistance is available for CLARION from the insurance reimbursement department at Advanced Bionics. The insurance department works with the individual, the implant center and the insurance company to help potential implant users receive the maximum coverage available through their insurance carriers.

***Is CLARION covered under warranty?***

CLARION is designed to withstand the wear and tear of daily life. The implanted components are warranted for ten years, while the speech processor has a three-year warranty. Over time, the batteries and cables may need to be replaced. When first receiving the system, spare batteries, cables and accessory equipment are provided.

***Who developed and designed CLARION?***

CLARION is the result of many years of extensive research and development and represents the cooperative efforts of the University of California, San Francisco (UCSF), Research Triangle Institute (RTI), and the device manufacturer, Advanced Bionics Corporation.

For over twenty years, UCSF has been engaged in cochlear implant research and development. Research has focused on the design and production of a cochlear implant capable of differentially stimulating small regions of the auditory nerve. UCSF designed and developed the unique electrode array used with CLARION. Research at RTI has focused on the development of speech processing strategies for auditory prostheses and is recognized as a world leader in the modeling of the electrically-stimulated cochlea. Through their joint investigations, UCSF and RTI have demonstrated that each implant recipient may not be suited to the same speech processing strategy and that gains in speech recognition can be made by selecting the best type of processing for the individual patient. Advanced Bionics, the device manufacturer, has long been associated with the development and production of implantable devices requiring technological advances in hermetic packaging, integrated circuits, and signal processing.

***Will CLARION ever need replacing?***

The implanted device is designed to last a lifetime. However, despite extremely cautious and careful quality control and inspection, a device failure could occur. Because of the implant's unique bi-directional telemetry system, an internal device problem can be detected externally. In such an instance, it may be necessary to remove and replace the device.

CLARION is a state-of-the-art system and incorporates advanced techniques of signal processing and the most recent concepts in speech processing. Through its flexibility and transmission capabilities, it is designed to take advantage of and adapt to future speech processing strategies that may yield greater speech understanding. These potential advances may be provided to users of CLARION through a simple reprogramming of the speech processor. Thus, individuals implanted now may be able to benefit from future research without having to undergo a surgical replacement of the device. As cochlear implant technology continues to advance, however, some of the existing equipment may need to be replaced in order to take full advantage of new developments. If cochlear implant technology develops to the extent that new internal components are required, another surgical procedure would be needed. A total device replacement would then have to be considered.

***What is Advanced Bionics' commitment to the field of cochlear implants?***

Advanced Bionics is a spin-off from the second largest heart pacemaker manufacturer in the world. CLARION represents years of extensive research and development and the collaborative efforts of the some of the world's leading research institutions in the field of cochlear implants. Ongoing research continues and Advanced Bionics is committed to maintaining its position at the forefront of new technology and development.

Advanced Bionics is a company dedicated to enhancing the quality of life of its customers by providing outstanding service and producing the highest quality products.

***What advances can be expected in the field of cochlear implants?***

Several advances are anticipated in the future development of cochlear implants. Improvements are expected in the ability of the implant to provide better speech understanding as new speech processing strategies are developed. At several implant centers around the world, research is continuing on methods for estimating and mapping the location and magnitude of surviving auditory nerves. Once the pattern of nerve survival is known, the possibilities for providing individuals with a speech processing scheme optimally matched to the individual are greatly increased. Further miniaturization of the external components of devices is probable, with the promise of far smaller and lighter devices in the future. Thus, individuals currently implanted with the CLARION system may be able to take advantage of and benefit from ongoing implant research without requiring surgical replacement of implanted components.

***What should I expect from a cochlear implant team?***

Cochlear implant teams vary in composition and in the services that they provide. All teams will have a surgeon who performs the implant surgery and a pediatric audiologist who performs the audiological testing and programming of the speech processor. Some implant teams have deaf educators or speech-language pathologists who perform communication assessments and deliver the rehabilitation training. Other implant teams work closely with programs or professionals in the community who provide rehabilitative and educational services. Some implant teams also include a psychologist.

## XII. CONCLUSIONS

Clinical study of CLARION has demonstrated its benefits. Children have experienced a variety of benefits ranging from awareness of environmental sounds to the ability to understand speech without lipreading.

The decision to have your child receive a cochlear implant is a major one. There are several resources available that may help in making this choice. The most valuable source of information is the cochlear implant center. Each implant center has professionals, audiologists and surgeons specially trained in the field of cochlear implants. These individuals work as a team and will conduct an evaluation to determine implant candidacy. Moreover, they will explain the benefits and limitations of cochlear implants and counsel individuals and families regarding their expectations. Advanced Bionics, the manufacturer of CLARION, works closely with each of its implant centers to ensure that they have the latest information about CLARION. Additionally, the staff at Advanced Bionics is available to assist in providing information and service.

Organizations, such as Self Help for Hard of Hearing People (SHHH), Cochlear Implant Club International (CICI), the Alexander Graham Bell Association for the Deaf (AGBell) and the Network of Educators of Children with Cochlear Implants (NECCI) can provide general information as well as put you in touch with families who have experience with cochlear implants. Most importantly, however, may be the support of family and friends. Their support during the decision making process, the surgery, the fitting and rehabilitation process can be invaluable.

If you are interested in learning more about cochlear implants or in locating a CLARION cochlear implant center near you, please call or write Advanced Bionics Corporation:

Advanced Bionics® Corporation
12740 San Fernando Road
Sylmar, CA 91342 U.S.A.

800-678-2575 (Voice)
800-678-3575 (TDD)
818-362-7588 (Voice, outside the United States)
818-362-5069 (Fax)
www.cochlearimplant.com (Website)