AUG 3 1 2005

K052060

INTELLIGENT HEARING SYSTEMS

510(k) Summary

Prepared By:	Intelligent Hearing Systems 7356 SW 48th Street Miami, FL 33155
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Contact Person:	Edward Miskiel
Date Summary prepared:	July 26, 2005
Name of the Device:	Opti-Amp DC-Powered
Common Name:	Evoked Potential Amplifier
Classification Name:	Physiological Signal Amplifier (per CFR 882.1835)
Predicate Device:	Opti-Amp (K914876)
Device Description:	Opti-Amp DC-Powered is a bio-amplifier testing device (made up of a transmitter and receiver) that is capable of acquiring evoked potentials.
Intended Use:	The intended use of the Opti-Amp DC-Powered device is to acquire evoked potentials. This is the **same intended** use as that of the original IHS Opti-Amp, which was previously cleared as 510(k) number K914876.
Technological Characteristics:	The Opti-Amp DC-Powered device is similar to the predicate device in its intended use and methodologies. The intended use of the device has not changed as a result of modifications to the general or electrical specifications of the device. The Opti-Amp DC-Powered device technologically differs from the predicate device in that the power supplied to the Opti-Amp DC-Powered Transmitter device is provided by a medical grade power supply with additional protection provided by a high isolation voltage DC-DC converter. The power supplied to the predicate device's transmitter is provided by commercially available dc batteries (housed internally).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2005

Intellegent Hearing Systems
c/o Edward Miskiel, PhD
President & CEO
7356 S. W. 48th Street
Miami, Florida 33155

Re: K052060
Trade/Device Name: OPTI-AMP DC-Powered
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: July 26, 2005
Received: July 29, 2005

Dear Dr. Miskiel

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Evenette N Beers PhD

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: Indications for Use

510(k) Number (if known): K052060

Device Name: Opti-Amp DC-Powered

Indications for Use:

The intended use of the Opti-Amp DC-Powered is as a physiological signal amplifier. It is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting.

The anatomical site of contact is the patient's outer skin surface with electrodes placed to acquire a bio-electric surface signal.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K052060