Neuro-Biometrix, Inc.

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MAR 23 1998

K 973740

Appendix 9

510(K) Summary.

Contact Person:	Michael H. Arenberg
Date Summary Prepared:	September 29, 1997
Trade Name:	Round Window E-Cath™ (RW E-Cath™)
Common Name:	Middle Ear Catheter with Electrocochleography Electrode
Classification Name:	Class II

Equivalence: The RW E-Cath™ is substantially equivalent to the combination of the following legally marketed predicate devices; (1) the Round Window μ Cath™; (2) the Ear Electrode; and (3) the Transtympanic Needle Electrode. The RW E-Cath™ and the combination of the predicates have the same indications for use, and pose substantially similar risks..

Description: The RW E-Cath™ is an accessory to a tympanostomy tube. The RW E-Cath™ consists of a single triple-lumen tube opening into a hollow fenestrated reservoir tip on the distal end. Two lumens are empty and are intended to allow fluid inflow and outflow. The third lumen encases the electrode wire lead and insulates it from the other two lumens. The atraumatic blunt distal tip of the electrode is the only part of the electrode that is exposed. The exposed distal tip of the electrode is located on the outside edge of the distal tip where it is intended to come into contact with the floor of the bony round window niche. The proximal end of the electrode contains a lead connector which the treating physician or audiologist can attach to a standard evoked potential recording instrument.

Intended use: The RW E-Cath™ is indicated for irrigation of the middle ear including the round window area of the middle ear and/or the recording of evoked electrophysiological inner ear potentials.

Principles of Operation: The inflow lumen is designed to allow fluid to be delivered from the proximal end of the device to the distal reservoir tip, where it can exit the device via fenestrations in the soft, flexible reservoir tip. The outflow lumen is intended to (1) relieve or avoid a build up of air and/or fluid pressure in the device; and (2) facilitate the removal of fluid from the device. The inflow-outflow design is intended to allow the treating physician to, without removing the device, add additional fluid, remove fluid or flush the system completely and refill it with new fluid. The third lumen contains the electrode leaving the blunt end exposed at the distal tip of the device where it can pick up stimulus dependent electrophysiological potentials from the cochlea and auditory nerve.

Technological Characteristics: The RW E-Cath™ and the predicate devices, the Round Window μ Cath™, the Ear Electrode, and the Transtympanic Needle Electrode are constructed of

class VI biocompatible materials (even though the electrode materials are different). Each has been subjected to biocompatibility testing.

Performance Testing: A bench test protocol was developed to assess the performance of the RW E-Cath™ in terms of pressure vs. flow, distal tip bond strength, tensile strength of the catheter body, proximal hub bond strength, and electrode integrity. All tests will be conducted on final sterile product. Sufficient samples will be used for each test. Each sample will also be visually inspected for workmanship and dimensional compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1998

Michael H. Arenberg
Vice President
Neuro-Biometrix, Inc.
7995 East Prentice Ave. Suite 110
Greenwood Village, CO 80111

Re: K973740
Round Window E-Cath™
Dated: January 15, 1998
Received: January 16, 1998
Regulatory class: II
21 CFR 874.3880/Procode: 77 ETD
21 CFR 882.1320/Procode: 84 GXY

Dear Mr. Arenberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K973740

3) Statement of Indications For Use

The Round Window E-Cath™ is indicated for irrigation of the middle ear including the round window area of the middle ear and/or the recording of evoked electrophysiological inner ear potentials.

David A. Jeyson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973740

Prescription Use ✓
(Per 21 CFR 801.109)