



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Julien Chaussy
Managing Director
Synapsys, Inc.
150-10 132nd Avenue
Jamaica, New York 11434

DEC 1 8 2001

Re: K012415

Trade/Device Name: Auris AEP
Regulation Number: 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: September 19, 2001
Received: September 24, 2001

Dear Mr. Chaussy:

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.

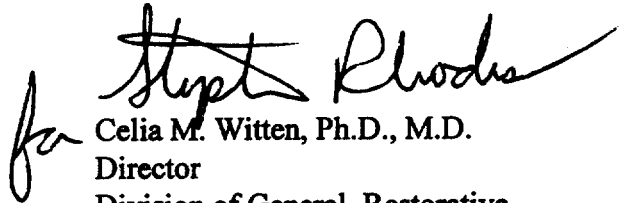
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 012415
Device Name: AURIS ABR

Indications For Use:

The AURIS I and AURIS II ABR Systems provide information regarding the functional integrity of the peripheral and central auditory system. It tests for auditory evoked potentials as an aid in detecting hearing loss and lesions in auditory pathways. It is intended for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders.

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

Steph Rhoads
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012415

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use