



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 15 1997

Raymond A. Enroth  
Manager of Regulatory Affairs  
Bernafon -Maico Inc.  
9675 West 76<sup>th</sup> Street  
Eden Prairie, MN 55344

Re: K974211  
Opus 2 - Full Concha Series - ITE  
Dated: November 7, 1997  
Received: November 10, 1997  
Regulatory class: I  
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Enroth:

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.

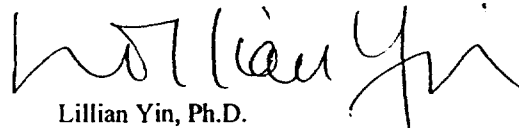
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, 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.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that electromagnetic interference from digital cellular telephones, as well as from other sources is increasingly becoming a concern. Typically, this interference takes the form of a buzzing sound that can range from annoying to very loud and may render a hearing aid temporarily ineffective for the wearer. Because electromagnetic interference may affect your device, you may be asked to test for electromagnetic compatibility in the future. In this interim period, we encourage you to modify your device labeling to inform practitioners and users of the potential for electromagnetic interference. Please be aware that a 510(k) submission is required for any claims that infer that your device is compatible with potential sources of electromagnetic interference, such as "compatible with digital cellular telephones", and that data supporting such claims is necessary.

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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin". The signature is fluid and cursive, with the first name "Lillian" written in a larger, more prominent script than the last name "Yin".

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

510 (k) Number ( if know ): \_\_\_\_\_

Device Name: OPUS 2 - FULL CONCHA SERIES - ITE

Indications For Use:

A. General Indications:

The intended use of this model hearing aid is to amplify sound pressure waves and transmit the signal to the external ear, through the medium of air, to compensate for impaired hearing. This device is indicated for individuals with losses in the following categories:

**Severity:**

- 1. Slight
- 2. Mild
- 3. Moderate
- 4. Severe
- 5. Profound

**Configuration:**

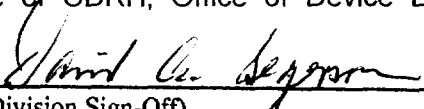
- 1. High Frequency  
- Precipitously Sloping
- 2. Gradually Sloping
- 3. Reverse Slope
- 4. Flat
- 5. Other \_\_\_\_\_

**Other:**

- 1. Low Tolerance  
To Loudness
- 2. \_\_\_\_\_
- 3. \_\_\_\_\_

( 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 Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K974211

Prescription Use \_\_\_\_\_  
( Per 21 CFR 801.109 )

OR

Over - The - Counter Use \_\_\_\_\_

(Optional Format 1 - 2 - 96)

Restricted Device  
Per 874.420 and 421