

K974365

SUMMARY OF SAFETY & EFFECTIVENESS

JAN 22 1998

Based on previous experience of middle ear prostheses, there is no reason to believe that the proposed prosthesis, or the material from which it is constructed, will have any detrimental effect on the condition of the patient. The available data indicate that hydroxylapatite does not alter with time in any way that might have an adverse effect on the patient or on the efficiency of the reconstruction. Should the reconstruction fail, it is likely that the prosthesis would be extruded from the ear without causing any harm. The prosthesis will not be harmful to the user or any third party.

I therefore affirm, as an otologist of many years' experience, that this device will be completely safe and effective in use.



R. P. Mills, MS. MPhil, FRCS
Consultant ENT Surgeon



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Margaret Blackmore
Regulatory Affairs
Exmoor Plastics
Lisieux Way
Taunton, TA1 2LB, U.K.

Re: K974365
Mills Sleeve Prosthesis
Dated: November 10, 1997
Received: November 19, 1997
Regulatory class: II
21 CFR 874.3450/Procode: 77 ETB

JAN 22 1998

Dear Ms. Blackmore:

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.

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,

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

Device Listing Number: A895750

A895750

510(k) Number (if known): K974365

Device Name: MILLS SLEEVE PROSTHESIS

Indications for Use:

Any gap in the ossicular chain caused by erosion of the incus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974365