



APR - 1 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alastair Winn
Medisil Corporation
1735 N. Olive Street
Ventura, California 93001

Re: K040042

Trade/Device Name: Medisil Silicon Sheeting
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose and throat synthetic polymer material
Regulatory Class: II
Product Code: MIB
Dated: January 6, 2004
Received: January 12, 2004

Dear Mr. Winn:

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.

Page 2 - Mr. Alastair Winn

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) 594-4659. 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/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
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

Indications for Use

510(k) Number K040042

March 25, 2004

(Revised from March 4, 2004 Version)

(Revised from March 15 Version)

(Revised from March 17 Version)

Device Name: Medisil Silicone Sheeting

Indications For Use:

Sheeting is indicated for short term use for nasal splinting, wound dressings, scar coverings and temporary joint spacers.

For long term use, this device is indicated for tympanic membrane repair, dural covering, nasal septal repair, tendon anastomosis and neural repair, correction of strabismus, galea repair, orbital floor repair, hemodialysis shunt anchors, facilitation of osteogenesis, repair of urethral strictures, staged repair of omphalocele and repair of orbital floor fractures.

Prescription Use- Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use- No
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K040042