K041704 page 1/2

OCT 17 2005

510K Summary

NewMedical Technology, Inc

3324 Commercial Avenue
Northbrook, IL 60062 USA
847-412-1000 Main
847-412-1001 Fax

Date of Submission: February 15, 2004

The NewGel Plus introduced by *NewMedical Technology, Inc.*, is a device which substantially equivalent to other marketed silicone gel sheets. Indications for use are substantially the same, that is, topical treatment of scars.

The advantages over other marketed devices from other vendors include the size of the strips in the package to enhance ease of use.

In summary, the features incorporated into the *NewMedical NewGel Plus* have specific advantages over other substantially equivalent products to enhance ease of placement/ application along with the care and comfort of the patient. Neither one of the above features will raise any safety concern because they don't change any of the basic design concepts compared to other similar approved devices.

Equivalence To Marketed Devices:

Equivalency of the *NewMedical NewGel Plus,* is based on similarities in intended use, materials, design and operational principles to the predicate silicone gel sheeting.
The features of the *NewMedical NewGel Plus* and the named predicate devices are substantially equivalent in the management of closed scars.

1-Intended Use:

All of the named devices, and the *NewMedical NewGel Plus*, are intended to be used in the management of hypertrophic and/or keloid scars.

2-Materials:

The materials used in the manufacturing of the *NewMedical NewGel Plus are* medical grade of silicone gel and natural alpha-tocopherol (Vitamin E). Vitamin E is only used to improve the tackiness characteristics of the gel sheet during handling (see Appendix 5). The materials conform to MSDS for silicone gel, MSDS for alpha-tocopherol, MSDS for polypropelene mesh, MDSD for polyurethane packaging tray. Silicone gel have a long history of successful clinical usage. Silicone Gel is used in the manufacturing of Cica-Care adhesive gel sheeting by Smith & Nephew Medical Ltd., Hull HU3 2BN, and in TopiGel silicone gel sheeting by CUI Corporation, Santa Barbara, CA.

3- Design:

The basic design features of the *NewMedical NewGel Plus* is substantially equivalent to the predicate devices. The subject devices and the named devices are adhesive methods of scar management. The subject devices and the

named devices have similar reinforcement materails. The subject devices and the predicate devices use similar non-stick backings. The subject devices and the predicate devices are supplied in similar transparent trays. The subject devices and the predicate devices use components that have a long history of safe clinical use and FDA review, acceptance and clearance to market.

4- Operational Principles:

The basic operational principles for the named device and the subject device are similar – mainly in site preparation, method of application, ease of use and replacement, precautions, indications, and components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Haitham Matloub
VP Technology
NewMedical Technology, Inc.
3324 Commercial Avenue
Northbrook, Illinois 60062

Re: K041704
Trade/Device Name: NewGel Plus
Regulation Number: 21 CFR 878.4025
Regulation Name: Silicone sheeting
Regulatory Class: I
Product Code: MDA
Dated: September 20, 2005
Received: September 28, 2005

Dear Mr. Matloub:

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), please contact the Office of Compliance at (240) 276-0115. 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/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting 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 (if known): K041704

Device Name: NewGel Plus

Indications For Use: For the management of hypertrophic and keloid scars

Prescription Use __X___ AND/OR Over-The-Counter Use X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, ~~Office of In Vitro Diagnostic Devices (OIVD)~~ Office of Device Evaluation (ODE)

510(k) Number K041704