

AUG 13 1999

GUIDELINES INCORPORATED

SKIN 2 forte
510(k) Notification
United Hospital Technologies, Inc.

K990651

I. 510(k) Summary

Trade Name – SKIN 2 *forté*™ Silicone Sheeting

Common Name – silicone sheeting

Classification Name – Silicone elastomer for scar management

Substantial Equivalence

The new product is substantially equivalent to the currently marketed ReJuviness product manufactured and marketed by RichMark International Corp. (K974380). The ReJuviness product is offered for sale as an “over the counter” product.

Description

Skin 2 *forté* Silicone Sheeting is a non-surgical, medically proven product that can help reduce your old scars and prevent new scars from developing. Skin 2 *forté* softens, smoothes and flattens scar tissue and restores a more normal skin color and texture. Consistent use of the SKIN 2 *forté* system can reduce hypertrophic and keloid scars.

Indications for Use

SKIN 2 *forté* Silicone Sheeting is indicated for the management of hypertrophic and keloid scars. Consistent use of SKIN 2 *forté* can reduce hypertrophic and keloid scars.

SKIN 2 *forté* may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic and keloid scars. SKIN 2 *forté* may be used as soon as the wound is closed, dry and the sutures or staples have been removed.

Biocompatibility Studies

SKIN 2 *forté* Silicone Sheeting is composed of a biomedical silicone elastomer that has been extensively evaluated for biocompatibility during limited and prolonged patient exposure, based on currently recognized regulatory requirements (ISO 10993-1, “Biological Testing of Medical and Dental Materials and Devices, Part 1: Guidance on Selection of Tests” and “Tripartite Biocompatibility Guidance for Medical Devices.”) Results from this testing are summarized in the table below.

Biocompatibility of Biomedical Grade Silicone Elastomer		
TEST	SAMPLES TESTED	OUTCOME
Cell culture with Neutral Red Uptake	Elastomer	No Cytopathic effects (morphology Change)
	Cell culture medium extract of elastomer	No Cytopathic effects (morphology Change)
Ames Bacterial Reverse Mutagenicity	Acetone extract of elastomer	No evidence of genetic activity or cytotoxicity
	Saline extract of elastomer	No evidence of genetic activity of cytotoxicity
Hemolysis	Elastomer	Nonhemolytic
	Saline extract of elastomer	Nonhemolytic
USP Pyrogen	Saline extract of elastomer	Nonpyrogenic
USP Class V Extractables	Extracts of elastomer in:	
System Toxicity	Saline	Nonirritating and nontoxic relative to controls
Intracutaneous Reactivity	5% ethanol in saline	Nonirritating and nontoxic relative to controls
	Polyethylene 400	Nonirritating and nontoxic relative to controls
	Cottonseed oil	Nonirritating and nontoxic relative to controls
Skin Sensitization	Elastomer	No sensitization
	Saline Extract	No Sensitization
	Ethanol or acetone extract	No sensitization
90-day Implant	Elastomer	Reaction equivalent to or lesser than negative control



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

United Hospital Technologies, Inc.
c/o Mr. Samuel Swetland
Vice President, Regulatory Affairs and Compliance
Guidelines, Inc.
10320 USA Today Way
Miramar, Florida 33025

Re: K990651
Trade Name: Skin 2 Forte Silicone Sheeting
Regulatory Class: Unclassified
Product Code: MDA
Dated: June 24, 1999
Received: June 25, 1999

Dear Mr. Swetland:

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 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). 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.

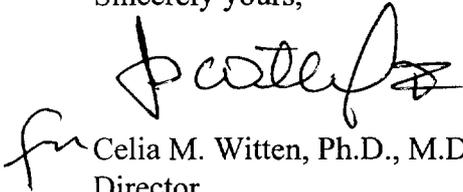
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 – Mr. Samuel Swetland

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) 594-4595. 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 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/dsma/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990651

Device Name: SKIN 2 fortē Silicone Sheeting

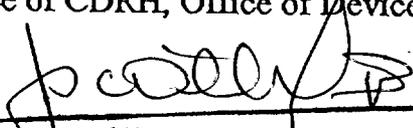
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices K990651
510(k) Number _____

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X