

510K SUMMARY

APR - 3 1998

RE: REJUVENESS
510(K) K974380

RICHMARK INTERNATIONAL CORP
100 SARATOGA VILLAGE BLVD.
BALLSTON SPA, NY 12020

REJUVENESS IS A SOFT, DURABLE REUSABLE SILICONE OCCLUSIVE SHEETING. IT IS A MEDICAL-GRADE, PURE SILICONE SHEETING THAT IS MANUFACTURED IN THE USA.

REJUVENESS IS A NON-INVASIVE MEDICAL DEVICE THAT REDUCES HYPERTROPHIC AND KELOID SCARS RESULTING FROM BURNS, SURGICAL PROCEDURES AND TRAUMATIC EVENTS. IT SOFTENS, SMOOTHES AND FLATTENS SCARS AND RESTORES THEM TO A MORE NORMAL TEXTURE AND COLOR. WHEN USED DAILY AS DIRECTED, REJUVENESS HAS THE POTENTIAL TO DRAMATICALLY IMPROVE THE APPEARANCE OF BOTH OLD AND NEW SCARS. REJUVENESS HAS BEEN CLINICALLY PROVEN EFFECTIVE IN THE MANAGEMENT OF HYPERTROPHIC AND KELOID SCARS AND MAY RELIEVE THE BURNING AND ITCHING THAT IS CHARACTERISTIC OF SCARRING DISORDERS. REJUVENESS HAS ALSO SHOWN SUCCESS IN THE PREVENTION OF HYPERTROPHIC AND KELOID SCARS WHEN APPLIED FOLLOWING SURGICAL PROCEDURES.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Piccolo
Richmark International Corporation
100 Saratoga Village Boulevard
Ballston Spa, New York 12020

APR - 3 1998

Re: K974380
Trade Name: Rejuveness
Regulatory Class: Unclassified
Product Code: MDA
Dated: February 19, 1998
Received: February 23, 1998

Dear Mr. Piccolo:

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.

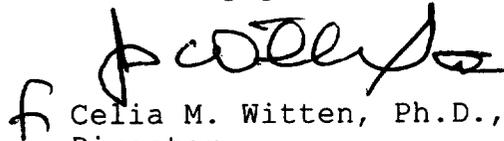
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (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,



f 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

Page _____ of _____

510(k) Number (if known): K974380/S1

Device Name: ReJuveness Silicone Sheeting

Indications For Use:

MANAGEMENT OF HYPERTROPHIC AND KELOID SCARS

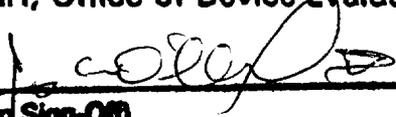
- ReJuveness™ is effective in the management of hypertrophic and keloid scars.
- Consistent use of ReJuveness™ can reduce hypertrophic and keloid scarring.

PREVENTION OF HYPERTROPHIC AND KELOID SCARS

- ReJuveness may be useful as a prophylaxis on closed scars to aid in the prevention of hypertrophic and keloid scarring.
- If used following surgical procedures, ReJuveness™ may prevent hypertrophic and keloid scarring.
- ReJuveness™ can be used as soon as the wound is closed, dry and the sutures have been removed.
- ReJuveness™ may prevent scarring disorders.

(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
 510(k) Number K974380

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)