JUL 3 0 2004

Attachment 2

510(k) Summary - Revised

Submitted By:	Prizm Medical, Inc. 3400 Corporate Way, Suite I Duluth, GA 30096	Phone: (770) 622-0933 Fax: (770) 622-9392
Contact Person:	Julie Stephens	
Date Prepared:	05/18/04	
Trade/Proprietary Name:	Thera-Cream™	
Common Name:	Electroconductive Cream	
Classification Name:	Electroconductive Media (21 CFR 882.1275)	
Product Code:	GYB, Neurology	
Legally Marketed Predicate Devices:	Conduct-Mist™ - 510(k) Numbers: K024181 & K951727; Conductive Aloe Vera Gel - 510(k) Number: K925466; SignaCreme® - 510(k) Number: K782055; Ultra/Phonic White - Preamendment; ReliefBand® Conductivity Gel: 510(k) Number K020180	

Device Description:

The Prizm Medical Inc.'s Thera-Cream™ product is used prior to electrode placement to reduce the impedance (resistance to alternating current), which increases the skin conductivity during electrotherapy treatment. Electrotherapy treatment includes the use of TENS (Transcutaneous Electrical Nerve Stimulators) and NMES (Neuromuscular Electrical Stimulators).

Intended Use:

Thera-Cream™ is a conductive cream, which increases skin conductivity for electrotherapy treatment and was developed for use with the Prizm brand electrotherapy units and the Intelligent Textiles® brand of garment electrodes.

Similarities and Differences of the Thera-Cream™ product to the Predicate Device:

Similarities

The Prizm Medical Inc.'s Thera-Cream™ product has the same intended use as the predicate products. Specifically, both the Conduct-Mist™ product and the Thera-Cream™ product use "conductive copper salts" which "increases the skin conductivity".

Attachment 2 (Continued)

510(k) Summary - Revised

Differences

The Prizm Medical Inc.'s Thera-Cream™ product utilizes a "moisturizing cream base" combined with the "conductive copper salts" that is rubbed onto the skin surface prior to garment electrode placement. The Conduct-Mist™ product utilizes a liquid/water base combined with the "conductive copper salts" that can be sprayed on the skin surface prior to garment electrode placement.

The Prizm Medical Inc.'s Thera-Cream™ product utilizes a "moisturizing cream base" which moisturizes skin. The Conduct-Mist™ product does not contain moisturizing ingredients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Prizm Medical, Inc.
C/o Ms. Julie Stephens
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K032239
Trade/Device Name: Thera-Cream™
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: II
Product Code: GYB
Dated: May 18, 2004
Received: May 19, 2004

Dear Ms. Stephens:

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.

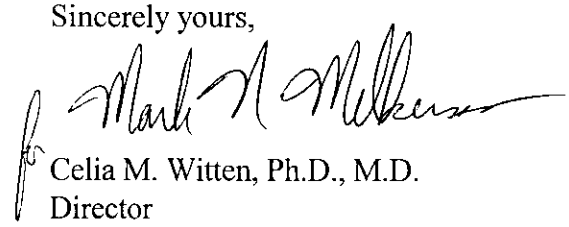
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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,



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 (if known): K032239

Device Name: Prizm Medical, Inc. Thera-Cream™

Indications for Use:

Thera-Cream™ is a conductive cream, which increases skin conductivity for electrotherapy treatment and was developed for use with the Prizm brand electrotherapy units and the Intelligent Textiles® brand of garment electrodes.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032239