7.0 510(k) Summary

1. Sponsor

SEP 1 3 2002

The Dezac group
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Cheltenham
Glos.
GL53 7HG
United Kingdom
Registered in England No. 2186341

Contact Person	Mr Kevin Herbert, Project Engineer
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2. Device Name

Trade Name of Device	Conductive Gel
Common Name	Electrolytic Gel
Classification name	Media, Electroconductive
Product Code	GYB
Regulation Class	IIa
Regulation Number	882.1275

3. Indications for Use

The Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulators) and EMS (electrical muscle stimulators). The Conductive Gel is used with external electrodes to reduce the impedance of the contact between the electrode surface and the skin.

4. Device Description

The Conductive Gel is a colored gel used for reducing the impedance between electrodes and the skin. The gel is to be generously applied to the area under an electrode, which is to be used. The gel can be washed off the skin after use.

5. Basis for Substantial Equivalence

Predicate Device

Skylark Batch #6060 Conductive Gel

K983964
Skylark Device Co Ltd.
34 Chung Shan North Road
12th Floor, Sec 3
Taipei, Taiwan

The Conductive Gel is substantially equivalent to Class IIa gels that are also indicated for use with TENS (transcutaneous electrical nerve stimulators) and EMS (electrical muscle stimulators). Conductive gel is used with external electrodes to reduce the impedance of the contact between the electrode surface and the skin. The gel is safe and effective for the conduction of electrical signals for the given indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

The Dezac Group
c/o Ms. Wendy Parsley
Senior Associate, Regulatory Affairs
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K022006
Trade/Device Name: Conductive Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB
Dated: June 18, 2002
Received: June 19, 2002

Dear Ms. Parsley:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known):_____K022006

Device Name:_____Conductive Gel

Indications For Use:

The Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulators) and EMS (electronic muscle stimulators). The Conductive Gel is used with external electrodes to reduce the impedance of the contact between the electrode surface and the skin.

(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
and Neurological Devices

510(k) Number K022006

(Optional Format 3-10-98)