7.0 510(k) Summary

1. Sponsor

SEP 13 2002

The Dezac group
54-56 Bath Road
Cheltenham
Glos.
GL53 7HG
United Kingdom
Registered in England No. 2186341

Contact Person	Mr Kevin Herbert, Project Engineer
Phone	+44 1242 702300
Fax	+44 1242 702301
Email	kherbert@dezac.co.uk

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)

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

2

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)

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 19, 2002

THE DEZAC GROUP
C/O M SQUARED ASSOCIATES, INC.
719 A STREET NE
WASHINGTON, DC 20002
ATTN: WENDY PARSLEY

510(k) Number: K022006
Received: 19-JUN-2002
Product: CONDUCTIVE GEL

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh.ode/A02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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K022006

FDA/CDRH/ODE/DHC

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CDRH SUBMISSION COVER SHEET

DATE OF SUBMISSION: June 18, 2002 FDA DOCUMENT NUMBER: _____

Section A Type of Submission

PMA
- ☐ Original submission
- ☐ Modular submission
- ☒ Ammendment
- ☐ Report
- ☐ Report Ammendment

PMA Supplement
- ☐ Regular
- ☐ Special
- ☒ Panel Track
- ☐ 30-day Supplement
- ☐ 30-day Notice
- ☐ 135-day Supplement
- ☐ Real-time Review
- ☐ Amendment to
- ☐ PMA Supplement

PDP
- ☐ Presubmission Summary
- ☐ Original PDP
- ☐ Notice of intent to start clinical trials
- ☐ Intention to submit Notice of Completion
- ☐ Notice of Completion
- ☐ Amendment to PDP
- ☐ Report

510(k)
- ☒ Original submission:
  - ☐ Traditional
  - ☐ Special
  - ☐ Abbreviated
- ☐ Additional Information:
  - ☐ Traditional
  - ☐ Special
  - ☐ Abbreviated

Meeting
- ☐ Pre-IDE meeting
- ☐ Pre-PMA meeting
- ☐ Pre-PDP meeting
- ☐ 180-Day meeting
- ☐ Other (specify)

IDE
- ☐ Original submission
- ☒ Amendment
- ☐ Supplement

Humanitarian Device Exemption
- ☐ Original- submission
- ☐ Amendment
- ☐ Supplement
- ☐ Report

Class II Exemption
- ☐ Original submission
- ☐ Additional information

Evaluation of Automatic Class III Designation
- ☐ Original submission
- ☐ Additional information

Other Submission
Describe submission:

RECEIVED JUN 18 02 FDA/CDRH/OCE/DID

Section B Applicant or Sponsor

Company/ Institution name: The Dezac Group

Establishment registration number: England 2186341

Division name (if applicable):

Phone number (include area code): (011) 44-1242-702300

Street Address: 54-56 Bath Road

FAX number (include area code): (011) 44-1242-702301

City: Cheltenham

State/Province: Glos., GL53 7HG

Country: United Kingdom

Contact name: Mr. Kevin Herbert

Contact Title: Project Engineer

Contact e-mail address: kherbert@dezac.co.uk

Section C United States correspondent (if different from above)

Company/ Institution name: M Squared Associates, Inc.

Establishment registration number:

Division name (if applicable):

Phone number (include area code): (202) 546-1262

Street Address: 719 A Street, NE

FAX number (include area code): (202) 546-3848

City: Washington

State/Province: D.C.

Country: United States of America

Contact name: Wendy Parsley

Contact title: Sr. Associate, Regulatory Affairs

Contact e-mail address: wparsley@msquaredassociates.com

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FROM FDA DRAFT 5/8/98

Section D1 Reason for Submission ----- PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☒ Manufacturing
  - ☒ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other
- ☐ Location change
  - ☒ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
    - ☐ Distributor
- ☐ Report submission:
  - ☒ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment
- ☐ Change in ownership
  - ☐ Change in correspondent

Section D2 Reason for Submission ------ IDE

- ☒ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☒ Termination of study
- ☐ Withdrawal of application
- ☐ Unaticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availibility
- ☐ Other reason (specify):

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol-feasibilty
- ☐ Protocol-other
- ☐ Sponsor

Report submission
- ☐ Current Investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

Response to FDA letter concerning
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final approval
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension of time to respond to FDA
- ☐ Request meeting

Section D3 Reason for Submission ------ 510(k)

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Other reason
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

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Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 GYB	2	3	4
5	6	7	8

Summary of, or statement concerning safety and effectiveness data:

- [X] 510(k) summary attached
- [ ] 510(k) statement

Information on devices to which substantial equivalence is claimed:

	510(k) Number	Trade or proprietary or model number	Manufacturer
1	K983964	Batch #6060 Conductive Gel	Skylark
2			
3			
4			
5			
6			

Section F — Product Information ----- Applicable to All Applications

Common or usual name or classification name:

	Trade or proprietary or model number	Model number
1	Conductive Gel	1
2		2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submisison: [ ] Laboratory testing [X] Animal Trials [ ] Human trials

Section G — Product Classification ----- Applicable to All Applications

Product code: C.R.F. Section: 882.1275

Classification panel: Gastroenterology / Urology

Device class:
- [ ] Class I
- [X] Class II
- [ ] Class III
- [ ] Unclassified

Indications (from labeling): 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.

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FROM FDA DRAFT 5/8/98

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract serilizer ☐ Repackager/rebuilder

Company/ Institution name: The Dezac Group	Establishment registration number: England 2186341
Division name (if applicable):	Phone number (include area code): 011-41-1242-702300
Street Address: 54-56 Bath Road	FAX number (include area code): 011-41-1242-702301

City: Cheltenham	State/Province: Glos., GL53 7HG	Country: United Kingdom

Contact name:Mr. Kevin Herbert

Contact title: Project Engineer	Contact e-mail address: kherbert@dezac.co.uk

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager/rebuilder

(b)(4)

[redacted]

FROM FDA DRAFT 5/8/98

m²

M Squared Associates, Inc.

June 18, 2002

Food & Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: **The Dezac Group – 510(k) Premarket Notification**

This is to notify FDA of the intent of The Dezac Group to market the Conductive Gel (Classification name: Media, Electroconductive) indicated 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.

This Premarket Notification is being submitted to allow this new device, the Conductive Gel, to be commercially distributed in the United States

Until such time that we are notified of clearance of this 510(k), we consider our intent to market this device as confidential commercial information and we request that it be considered as such by the FDA. We have not disclosed our intent to market this device to anyone, except employees and consultants of The Dezac Group, and we have taken precautions to protect this confidentiality.

In order to aid the reviewer, M Squared Associates will act as the U.S. correspondent. To eliminate time zone differences, please feel free to contact me questions or issues that requires immediate attention.

Sincerely,

Wendy Parsley

Wendy Parsley
Sr. Associate, Regulatory Affairs

M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002
Phone: 202-546-1262 ● Fax: 202-546-3848
www.msquaredassociates.com

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510(k) PREMARKET NOTIFICATION

CONDUCTIVE GEL

THE DEZAC GROUP

Submitted By:

The Dezac Group
54-56 Bath Road
Cheltenham
Glos.
GL53 7HG
United Kingdom
Registered in England No. 2186341

Mr. Kevin Herbert, Project Engineer
Telephone: +44 1242 702300
Fax: +44 1242 702301
Email: kherbert@dezac.co.uk

Device Manufacturer:

(b)(4) [redacted]

US Correspondent:

M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002
Ms. Wendy Parsley
Sr. Associate, Regulatory Affairs
Telephone: 202-546-1262
Fax: 202-546-3848

Submission Date: June 18, 2002

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TABLE OF CONTENTS

APPENDICES

1.0 TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87 (k)]

I certify that, in my capacity as Project Engineer of The Dezac group, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Kevin Herbert

(Signature)

Mr Kevin Herbert

Date: 10/5/02 (May 10, 2002)

*(Premarket Notification [510(k)] Number)

* For a new submission, leave the 510(k) number blank. Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not the consultant for the 510(k) submitter].

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2.0 Device Information

2.1 Applicant / Manufacturer Information

Submitted by	The Dezac group 54-56 Bath Road Cheltenham Glos. GL53 7HG United Kingdom
Device Manufacturer	(b)(4) [redacted]

Please address any written communication to Mr. Kevin Herbert, Project Engineer of The Dezac Group.

In order to aid the reviewer and eliminate time zone differences, please contact Ms. Wendy Parsley of M Squared Associates, Inc. at (202) 546-1262 or wparsley@msquaredassociates.com with any verbal or email communication or issue that requires immediate attention.

2.2 Device Name

Trade / Propriety Name	Conductive Gel
Common Name	Electrolytic Gel
Classification name	Media, Electroconductive
Panel code	Neurology
Product Code	GYB
Regulation Class	IIa
Regulation Number	882.1275

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2.3 Predicate Device

Trade / Proprietary Name	Batch #6060 Conductive Gel
Classification Number	IIa
Product Code	GYB
510(k) Reference Number	K983964
Regulation Number	882.1275
Decision date	12/09/1998
Applicant	Skylark Device Co. Ltd. 34 Chung Shan North Road 12th Floor, Sec 3. Taipei, Taiwan
Manufacturer	(b)(4) [redacted]

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3.0 Special Controls and Standards

3.1 Performance Standards

The gel is manufactured by (b)(4) and meets with all the acceptance criteria for irritation, sensitivity, preservation challenge or stability as required by 21 CFR 820.30. The Conductive Gel has CE & ISO9001 approval. A copy of certificate DNV is included in Appendix E.

(b)(4) sensitization trials have been conducted for the gel and show it to be safe and effective for the stated indications for use. The (b)(4) reports are included in Appendix B.

3.2 Voluntary Standards

This gel has been manufactured and tested in accordance with the requirements of the EC Directive and international standards ISO9001 and EN46001. (b)(4) is in accordance with MIL-STD-105E Level 4 for its quality inspection of goods.

The Dezac Group adheres to recognized and established industry practices and following continual assessment by (b)(4) has achieved the requirements of the following standards.

ISO 9002

The Dezac Group Quality Management Systems have been assessed and registered as meeting the requirements of ISO 9002, (b)(4)

ISO 13488, EN 46002

The Dezac Group Quality Management Systems have been assessed and registered as meeting the requirements of ISO 13488, EN46002, (b)(4)

CE 0120

The Dezac Group have been assessed and registered as meeting the requirements of Directive 93/42/EEC Annex V.

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4.0 Device Description

4.1 Reason for 510(k) Premarket Notification

This Premarket Notification is being submitted to allow a new electroconductive media, the Conductive Gel, to be commercially distributed in the United States by The Dezac Group. The Conductive Gel is manufactured by (b)(4)

The Conductive Gel is substantially equivalent to the FDA-approved Skylark Batch #6060 Conductive Gel. The Skylark gel (K0983964) was cleared by the FDA for the same indication for us as the Conductive Gel. The Skylark gel is also manufactured by (b)(4)

The Dezac Group wishes to gain FDA clearance for sale of the Conductive Gel under new branding and without significant change in labelling or indications for use as outlined in this application.

The Dezac Group and (b)(4) have been designing and manufacturing Conductive Gel for over 10 years and has since the product launch sold (b)(4) to European and Canadian markets.

4.2 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.

4.3 Device Description

The Conductive Gel is water-based to reduce the impedance of the contact between electrodes and the skin. It is supplied in 450 ml jars, 250 ml jars, 85 ml tubes, and 55 ml tubes. The gel is smeared across the skin in the area the electrode is to be placed.

4.4 Performance Specification / Technical Characteristics

The Conductive Gel is composed of the following ingredients:

- Carboxy Vinyl Polymer (b)
- Sodium Hydroxide (b)(4)
- Propylene Glycol (

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- Glycerin (b)
- Methyl parahydroxy benzoate (b)(4)
- Pigments ((b)
- Water

4.5 Non-Clinical Testing

Comparisons of the compositions for the Conductive Gel and the predicate Skylark Batch #6060 show identical results. The Conductive Gel is manufactured to, and has been independently tested to ISO9001, 1994 and EN46001, 1996. The Dezac Group and (b)(4) adhere to recognized and established industry practices, and all devices are subject to a final performance testing. (b)(4) adheres to MIL-STD-105E Level 4 for the inspection of the manufactured gel. A (b)(4) sensitization trial was carried out for the Conductive Gel. This trial found the gel to be safe for external use, and that it provides appropriate conduction for electrical stimulation.

The Dezac Group and (b)(4) have been designing and manufacturing Conductive Gel for over 10 years and has sold (b)(4) to European and Canadian markets without any incident since the product launch.

4.5.1 Financial Certification or disclosure Statement

In accordance with 21 CFR 807.87 (i) no financial certification or disclosure statement is necessary with this 510(k) application as no reference is made to clinical study data.

4.5.2 Labelling

A complete copy of all labels for the Conductive Gel is provided in Appendix C. In order to aid the reviewer in the comparison of the labelling with the predicate device, a copy of Skylark Batch #6060 Labelling is provided in Appendix D.

The proposed device is indicated 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.

To aid the reviewer, the contraindications, warnings, and precautions included in the labelling are repeated here.

Contraindications

- None

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Warnings

- For external use only.

Precautions

- Apply a generous amount of gel to each pad.
- Ensure the pad remains moistened throughout use.

4.6 Clinical Testing

A guinea pig sensitization positive control test has been conducted on the Conductive Gel at (b)(4) [redacted] The report for this trial is included in Appendix B. The report shows the Gel to be safe and no irritation was observed. The primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

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5.0 Substantial Equivalence Comparison

The Conductive Gel is substantially equivalent to Class IIa devices such as the Skylark Batch #6060 Conductive Gel. The Conductive Gel has an identical formula to that of the predicate Skylark Conductive Gel and is manufactured by the same manufacturer to identical standards. Both gels have the same indications for use.

5.1 Technical Characteristics

The Conductive Gel is composed of the following ingredients:

- Carboxy Vinyl Polymer (b)(4)
- Sodium Hydroxide (b)(4)
- Propylene Glycol (b)(4)
- Glycerin (b)
- Methyl parahydroxy benzoate (b)(4)
- Pigments (b)(4)
- Water

6.0 Indications for Use Statement

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.

7.0 510(k) Summary

1. Sponsor

The Dezac group
54-56 Bath Road
Cheltenham
Glos.
GL53 7HG
United Kingdom
Registered in England No. 2186341

Contact Person	Mr Kevin Herbert, Project Engineer
Phone	+44 1242 702300
Fax	+44 1242 702301
Email	kherbert@dezac.co.uk

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

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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.

APPENDIX A

MATERIAL SAFETY DATA SHEETS

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

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(b)(4) Data/Testing

(b)(4) Data/Testing

APPENDIX B

(b) (4) SENSITIZATION TRIALS

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

(b)(4) Data/Testing

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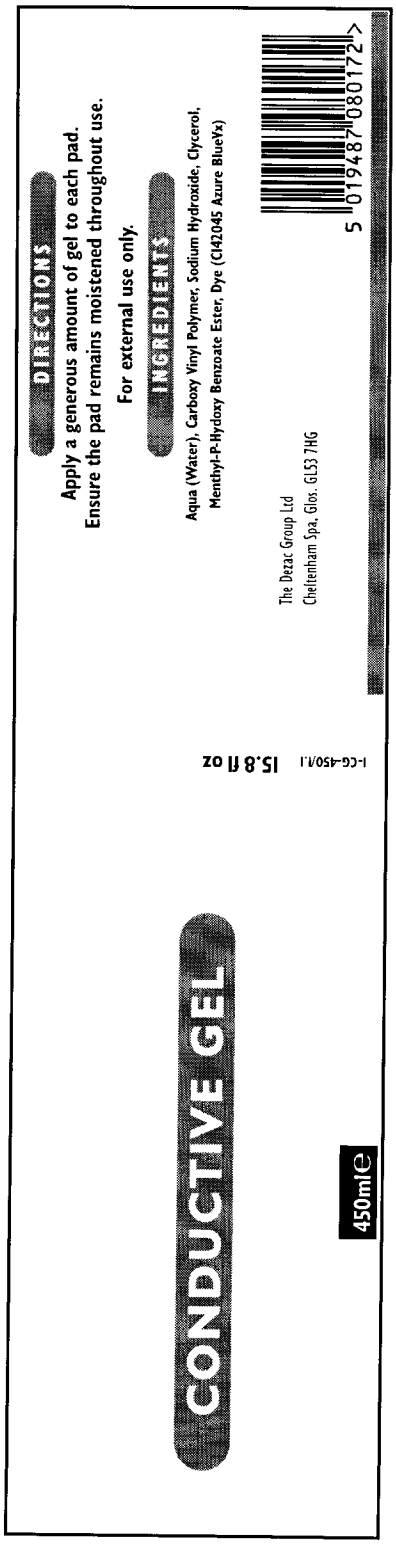
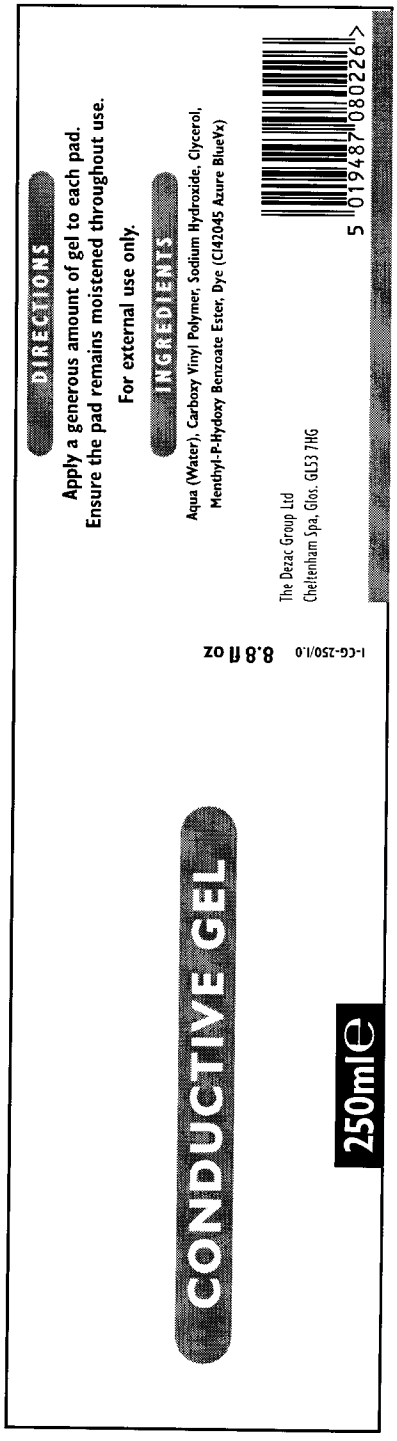
APPENDIX C

LABELING

CONDUCTIVE GEL





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APPENDIX D

LABELING

PREDICATE – SKYLARK GEL

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APPENDIX E

(b)(4)

QUALITY SYSTEM CERTIFICATE

(b)(4)

(b)(4)

510(k) REVIEW MEMORANDUM

Re: **K022006: Conductive Gel, The Dezac Group**

From: **Michael A. Eudy, Electrical Engineer, REDB/DGRD/ODE/CDRH**

Date: **9/12/02**

Contacts: **Wendy Parsley/Marie Marlow, M Squared Associates, Inc. 202-546-1262**

Device Summary:

This submission is for an electrode gel to be used with TENS and powered muscle stimulators.

The sponsor has clarified that this gel is identical in composition to the cleared as K983964, and they are repackaging the product, the gel is manufactured by (b)(4) [redacted] The sponsor has also provided the necessary biocompatibility teting information.

I requested that the sponsor clarify that this was the same gel and also make some additions to their labeling. The sponsor has faxed in this information and has agreed to add the following statements to their labeling:

Warnings:

- The long-term effects of electrode gel are unknown.
- Apply the electrode gel only to normal, intact, clean skin. Do not apply electrode gel over open wounds or over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Do not apply electrode gel over, or in proximity to, cancerous lesions.

Precautions:

- Some persons may experience skin irritation or hypersensitivity due to the electrode gel.
- Keep the electrode gel out of the reach of children.

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RECOMMENDATION:

Based upon the submission content to date, this device should be found substantially equivalent (SE) to legally marketed devices as follows;

Conductive Gel should be found substantially equivalent to legally marketed Electroconductive media (classified under 21 CFR 882.1275, class II, panel/product code 84/GYB).

Michael A. Eudy, Electrical Engineer, REDB/DGRD/ODE

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m²

M Squared
Associates, Inc.

September 12, 2002

Michael Eudy
DGRND
ODE / CDRH / FDA
9200 Corporate Blvd.
Rockville, MD 20850

VIA TELEFAX: 301-827-4349

RE: The Dezac Group – 510(k) Premarket Notification
Conductive Gel

Dear Mr. Eudy,

This fax follows up our telephone conversations and your e-mail this afternoon regarding the above referenced 510(k).

1. The Dezac Group Conductive Gel that is the subject of this 510(k) is identical in composition to the predicate product, Batch #6060 Conductive Gel distributed by Skylark (K983964). Both products are manufactured by (b)(4) [redacted]

2. The following statements will be added to the labeling for the Conductive Gel:

   Warnings:

   - The long-term effects of electrode gel are unknown.
   - Apply the electrode gel only to normal, intact, clean skin. Do not apply electrode gel over open wounds or over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
   - Do not apply electrode gel over, or in proximity to, cancerous lesions.

   Precautions:

   - Some persons may experience skin irritation or hypersensitivity due to the electrode gel.
   - Keep the electrode gel out of the reach of children.

Thank you for your cooperation and assistance throughout the review of this 510(k).

Sincerely,

Marie Marlow
Consultant to The Dezac Group

cc: Kevin Herbert

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K022006

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

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Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ___ No

Reviewer: [signature]

Concurrence by Review Branch: S Ruda

Date: 7-02

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	[redacted]	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K K022006

Reviewer: Mike Eudy

Division/Branch: DGAND / REDB

Device Name: Conductive Gel

Product To Which Compared (510(K) Number If Known): K983964

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 ~~If YES = Stop SE~~
8. New Types Of Safety Or Effectiveness Questions?			~~If YES = Stop NE~~
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Michael Eudy

Subject: 510(k) Number K022006

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

- ☒ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☐ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

GYB, 882.1275 Class II

Review: [signature] REOB 9/13/02
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 9/13/02
(Division Director) (Date)

Revised:8/17//99

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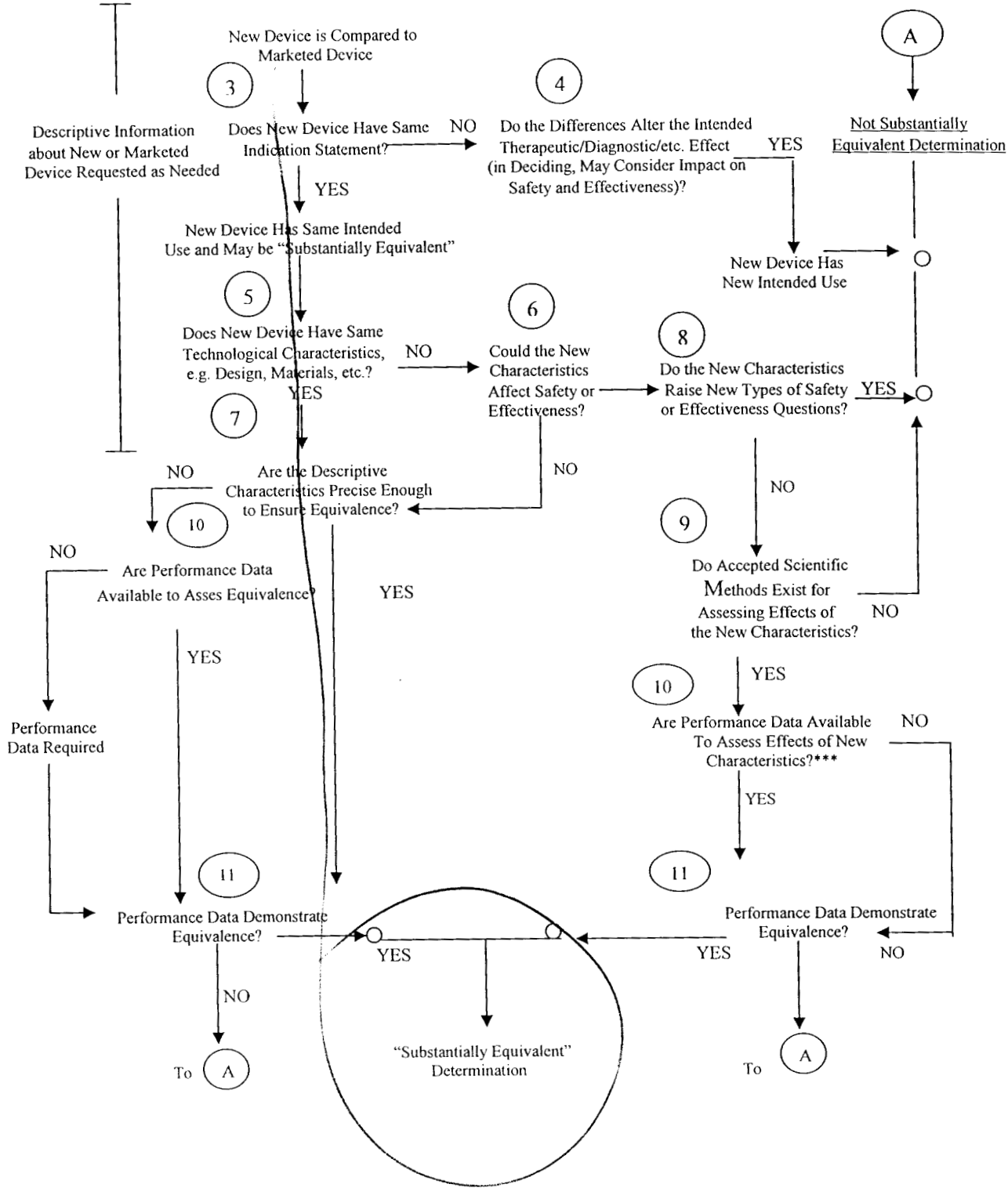
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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