Cortex Technology
510(k) Submission
DermaScan C Ultrasound System

510(k) Summary

(1) Submitter Information

Name: Cortex Technology

Address:

Textilvaenget 1
9560 Hadsund
Denmark

Telephone Number: 45-9857-2223

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: October 5, 1998

(2) Name of Device

Trade Name: Cortex DermaScan C Ultrasonic System
Common Name: Ultrasound Scanning System for Dermatological Applications
Classification name: System, Imaging, Pulsed-Echo, Ultrasonic, 90IYN.

(3) Equivalent legally-marketed devices.

The Derma-Scan C is identical to the version currently cleared in the United States, the DermaScan C Ultrasonic 3D skin scanner, K894834, assigned to the Brymill Corporation.

(4) Description

The Dermascan C transducer is a single-element 20 MHz mechanically-scanned transducer, mounted in a 2-D scanning hand-held probe. This probe generates B-scan images from which A and M mode scan lines can be derived.

The DermaScan C provides the following visualization modes:

a. 2-dimensional B-scan, displayed in real time
b. M-scan, displayed in real time
c. A-scan, as a "frozen" image derived from a B-scan line.

(5) Intended Use

The DermaScan C is an ultrasonic scanning system intended to be used to visualize the layers of the skin, including blood vessels, and to make approximate measurements of dimensions in the layers of the skin and blood vessels, by ultrasonic means.

(6) Performance Data

(a) Non-clinical tests

The software has all been revalidated for this submission.
The system has had ultrasonic emission tests conducted by an outside laboratory.
Electrical safety tests have been conducted on the device.

(b) Clinical tests

Since the DermaScan C is identical to a previously-cleared device, clinical tests are not required.

(c) Conclusions

The Derma-Scan C is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

George H. Myers, Sc.D.
Official Correpondent
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, N.J. 07604

Re: K983945
Cortex DermaScan C Ultrasonic System
Regulatory Class: II/ 21 CFR 892.1560
Product Code: 90 IYO
Dated: February 3, 1999
Received: February 8, 1999

Dear Dr. Myers:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Cortex DermaScan C Ultrasonic System, as described in your premarket notification:

Transducer Model Number

20 MHz

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

Page __1__ of __1__

510(k) Number (if known):K983945

Device Name: Cortex DermaScan C Ultrasonic Transducer

Intended Use: The DermaScan C ultrasonic transducer is intended to be used with the Cortex DermaScan C, an ultrasonic scanning system intended to be used to visualize the layers of the skin, including blood vessels, and to make approximate measurements of dimensions in the layers of the skin and blood vessels, by ultrasonic means.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)*	X	X	X							

Additional Comments:
*Clinical Application is "Dermatology"

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __✓__ (Per 21 CFR 810.109)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983945

Diagnostic Ultrasound Indications for Use Form

Page __1__ of __1__

510(k) Number (if known):K983945

Device Name: Cortex DermaScan C Ultrasonic System

Intended Use: The DermaScan C is an ultrasonic scanning system intended to be used to visualize the layers of the skin, including blood vessels, and to make approximate measurements of dimensions in the layers of the skin and blood vessels, by ultrasonic means.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)*	X	X	X							

Additional Comments:
*Clinical Application is "Dermatology"

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __✓__ (Per 21 CFR 810.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983945