JUL 1 3 2000

K993674
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Quantel Medical S.A..
510(k) Submission
"Pocket" Ultrasonic Pachymeter

510(k) Summary

(1) Submitter Information

Name: Quantel Medical S.A.

Address: 89, Boulevard Etienne Clémentel 63100
Clermont-Ferrand FRANCE

Telephone Number: +33 (0) 473-25-62-27

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 26, 1999

(2) Name of Device

Trade Name: "Pocket" Ultrasonic Pachymeter
Common Name: Ultrasonic Pachymeter for Measurement of Corneal thickness
Classification name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Equivalent legally-marketed devices.

1. Sonomed 200P Ultrasonic Pachymeter, K924311
2. DGH Model 500 Pachymeter, K920906

(4) Description

The POCKET is a small, hand-held ultrasonic Ophthalmic Pachymeter that uses the principles of sonar (pulsed ultrasound) to measure corneal thickness. The device allows the operator to pre-plan a series of measurements on the surface of the cornea, to go automatically from one to the other while making the

measurements, and then to present the results of the measurements as thickness over an area of the eye.

(5) Intended Use

The device is intended to be used for the measurement of corneal thickness by ultrasonic means, which is required for some types of corneal surgery.

(6) Performance Data

(a) Non-clinical tests

The POCKET has passed all tests for IEC 601-1 and 601-1-2. The unit has also had accuracy tests done by an outside laboratory.

Transducers have had output emissions done by an outside laboratory.

The Pocket software has undergone extensive validation testing.

(b) Clinical tests

Since the POCKET uses the same technology as existing devices, clinical tests are not required. However, it has been sold in Europe for several years and has not had reported problems.

(c) Conclusions

The Pocket pachymeter is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2000

Quantel Medical S.A.
c/o George H. Myers, Sc.D.
Official Correspondent
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K993674
Quantel Pocket Ultrasonic Pachymeter
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: June 16, 2000
Received: June 19, 2000

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 Quantel Packet Ultrasonic Pachymeter, as described in your premarket notification:

Transducer Model Number

P1 (20 MHz A-Scan)

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,

per David G. Segraves

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device Name: Quantel Medical S.A. "Pocket" Pachymeter

Intended Use: The Quantel Medical POCKET Ultrasonic Pachymeter is intended to be used for the measurement of corneal thickness by ultrasonic means, which is required for some types of corneal surgery.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic	N									
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)*										

Additional Comments:

(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 K993674