JUN 21 2002

K021683
1 of 2

Cinescan S
Ultrasonic Ophthalmic A and B scan System

510(k) Summary

Special 510(k)

(1) Submitter information

Name : Quantel Medical S.A.

Address:
21 rue Newton - Zone du BREZET
Clermont-Ferrand
63039 France

-

Telephone: 33-473-745 745

Contact person: Dr. George MYERS (Official Correspondent).

Medsys Inc.
377 Route 17 South
Hasbrouck Heights, New Jersey 07064
Tel : 201-727-1703
Fax: 201-727-1708

Date prepared : April 10, 2002

(2) Name of Device

Trade Name: "Cinescan S" Ophthalmic Ultrasound System
Common Name: Ophthalmic A and B scan ultrasound system
Classification name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Legally-marketed predicate device

The predicate devices are:
1. The "B-SCAN", K926521, manufactured by Biovision and then B.V.I (the predecessor company to Quantel Medical). This device included both A and B scan capability.
2. The Axis II, K000554, manufactured by Quantel Medical. This was the subject of a Special 510(k), and was also a modification of the "B-scan." A number of modifications cleared with the previous 510(k) (K000554) are also included in the Cinescan S.

Cinescan S
Ultrasonic Ophthalmic A and B scan System

510(k) Summary

(4) Description

The Cinescan S is a combined ophthalmic A and B scan system that can also be used for biometric measurements of the eye and for IOL calculations.

(5) Intended Use

The Quantel Medical Cinescan S is intended to be used for :

- the Axial Length measurement of the eye by ultrasonic means
- the implanted IOL power calculation, using the Axial Length measurement.
- Visualization of the interior of the eye by A and B scans.

(6) Performance Data

(a) Non-Clinical tests

- IEC 601-1 for Electrical Security
- IEC 601-1-2 for Electromagnetic Compatibility
- FDA transducer emissions tests

(b) Clinical tests

Since the Cinescan uses the same technology as existing devices, clinical tests are not required.

(7) Conclusion

The Cinescan S 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

JUN 21 2002

Quantel Medical S.A.
% George H. Myers, Sc.D.
Official Agent
Medsys, Inc.
377 Route 17 South
HASBROUCK HEIGHTS NJ 07604

Re: K021683
Trade Name: Cinescan S Ophthalmic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 HPR and IYO
Dated: May 20, 2002
Received: May 22, 2002

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket 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 Cinescan S, as described in your premarket notification:

Transducer Model Number

B-scan, 10MHz
STD-A A-scan, 8MHz
B-HF B-scan, 20 MHz

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 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, 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 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 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Page 1 of 4

510(k) Number (if known):

Device Name: Cinescan S

Intended Use: The intended use of the Cinescan S is for diagnostic imaging of the eye by A and B scans and for biometric measurements of the eye.

Mode of Operation

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

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021683

Diagnostic Ultrasound Indications for Use Form

Page 2 of 4

510(k) Number (if known):

Device Name: Cinescan S B-scan Transducer , 10 MHz
Intended Use: The intended use of the Cinescan S 10 MHz B-scan transducer is for diagnostic imaging of the eye by B scans..

Mode of Operation

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

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 810.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021683

Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device Name: Quantel Medical S.A. "STD-A" A-scan 8 MHz transducer for "Cinescan S"

Intended Use: The Quantel Medical Cinescan * Mhz A-scan transducer is intended to be used with the Quantel Cinescan S A-scans of the eye and for biometric measurements.

Mode of Operation

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

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 810.109)

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510(k) Number K021683

Diagnostic Ultrasound Indications for Use Form

Page 4 of 4

510(k) Number (if known):

Device Name: Cinescan S B-scan transducer B-HF 20 MHz

Intended Use: The intended use of the Cinescan S is for diagnostic imaging of the eye by B scans and for biometric measurements of the eye.

Mode of Operation

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

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Prescription Use ✓ (Per 21 CFR 810.109)

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