K102198

NOV - 5 2010

Section 5

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 08-06-10 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

Quantel Medical S.A.

21 rue Newton

ZI Le Brezet

63039 Clermont Ferrand Cedex 2

FRANCE

Tel: +33 (0) 473 745 745

Fax: +33 (0) 473 745 700

B. Contact Information

Quantel USA

601 Haggerty Lane

Bozeman, MT 59715

Tel: 406-586-0131

Fax: 406-586-2924

Contact person: Michael Johnson M.D.

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *COMPACT TOUCH* STS Ophthalmic Ultrasound System

Device Common Name: Ophthalmic Ultrasound System

Classification Name: Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560) and Diagnostic Ultrasound Transducer (21 CFR 892.1570).

Product Code: IYO and ITX, respectively

Panel: 86 Ophthalmic

Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *COMPACT TOUCH STS* uses similar technology and physical output characteristics as the following predicate devices:

k060626 Sonomed Inc. *VuMax* Ophthalmic Ultrasound System

E. Device Description [21 CFR 807.92(a)(4)]

The *COMPACT TOUCH STS* is an ultrasonic system designed for ophthalmic use. It performs B type scans for diagnostic imaging of the eye. It is not intended to be used for determining the power of implanted lenses, but rather is capable of making intra-ocular measurements. The system is composed of a main console controlled by a touch screen. It uses a B-scan probe (LIN50) which is a motor driven 50 MHz transducer.

F. Device Specifications [21 CFR 807.92(a)(6)]

The *COMPACT TOUCH STS* system includes a B-scan ultrasonic probe. The B-scan probe operates at 50 MHz and has an active diameter of 4.5 mm.

G. Indications for Use [21 CFR 807.92(a)(5)]

The Quantel Medical *COMPACT TOUCH STS* is intended to be used for diagnostic imaging and measurement of the eye including:

◆ Visualization of the interior of the eye by B scan

◆ Make measurements inside the eye (Sulcus to Sulcus, Irido Cornea Angle Left, Irido Cornea Angle Right, Lens curvature and Anterior Chamber Depth).

H. Performance Data [21 CFR 807.92(b)(2)]

Laboratory testing following the guidance "Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound systems and Transducers" (Sept 9, 200) was conducted to verify that the *COMPACT TOUCH STS* met design specifications and was substantially equivalent to the predicate devices. No Clinical testing is required.

I. Conclusion [21 CFR 807.92(b)(3)]

Technologically, the *COMPACT TOUCH STS* was found to be substantially equivalent to the currently cleared k060626 Sonomed Inc. VuMax Ophthalmic Ultrasound System. The indications for use are similar to these previously cleared devices. The risks and benefits for the *COMPACT TOUCH STS* are argued to be comparable to the predicate devices. We believe that there are no new questions of safety or efficacy raised by the introduction of the *COMPACT TOUCH STS.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building 66 – Room 5645
Silver Spring, MD 20993-0002

Quantel Medical S.A.
c/o Dr. Mike Johnson
QUANTEL USA
601 Haggerty Lane
BOZEMAN MT 59715

NOV - 5 2010

Re: K102198/S001
Trade/Device Name: COMPACT ACT TOUCH STS Ophthalmic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, and ITX
Dated: October 1, 2010
Received: October 1 2010

Dear Dr Johnson:

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 COMPACT TOUCH STS LIN50 ultrasound probe, as described in your premarket notification:

Transducer Model Number
LIN50

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 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

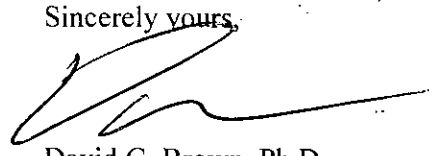
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 4

Indications for Use

K102198

NOV - 5 2010

510(k) Number (if known): not known

Device Name: "*COMPACT TOUCH STS*" Ophthalmic Ultrasound System

Indications for Use Statement:

The Quantel Medical *COMPACT TOUCH STS* is intended to be used for diagnostic imaging and measurement of the eye including:

◆ Visualization of the interior of the eye by B scan

◆ Make measurements inside the eye (Sulcus to Sulcus, Irido Cornea Angle Left, Irido Cornea Angle Right, Lens curvature and Anterior Chamber Depth).

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _X_ OR Over-The Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

Diagnostic Ultrasound Indications for Use Form

Page __1__ of __2__

510(k) Number (if known): NA

Device Name: *COMPACT TOUCH STS*

Intended Use: The Quantel Medical *COMPACT TOUCH STS* is intended to be used for diagnostic imaging and measurement of the eye including:

◆ Visualization of the interior of the eye by B scan

◆ Make measurements inside the eye (Sulcus to Sulcus, Irido Cornea Angle Left, Irido Cornea Angle Right, Lens curvature and Anterior Chamber Depth).

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic		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___X_____(Per 21 CFR 810.109)

Diagnostic Ultrasound Indications for Use Form

Page __2__ of __2__

510(k) Number (if known): NA

Device Name: *COMPACT TOUCH STS* LIN50 ultrasonic probe.

Intended Use: The Quantel Medical *COMPACT TOUCH STS* LIN 50 ultrasonic probe is intended to be used for diagnostic imaging and measurement of the eye including:

◆ Visualization of the interior of the eye by B scan

◆ Make measurements inside the eye (Sulcus to Sulcus, Irido Cornea Angle Left, Irido Cornea Angle Right, Lens curvature and Anterior Chamber Depth).

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic		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___X_____(Per 21 CFR 810.109)