

**7.0 QUANTITATIVE SENTINEL SYSTEM
510(k) SUMMARY**

Prepared 04 September 1999

[807.92(a)1] Contact Information

Maria Vitug Fouts
Sr. Regulatory Compliance Specialist

Address: GE Marquette Medical Systems, Inc.
200 Harry S. Truman Parkway, Suite 220
Annapolis, MD 21401

Phone: 410-573-6294

Fax: 410-897-0349

[807.92(a)2] Device Name and Classification

The proprietary name of the modified device to be introduced into interstate commerce is the Quantitative Sentinel System.

Common names include: QS, QS-5, QS System, QS Perinatal, QS-ICU, and QS-Surveillance, Surveillance & Archive, QS Unit Manager, QS Lab Access

As indicated in the original premarket notification submission, the Quantitative Sentinel System is a class II device. To date no formal classification name has been issued for software based clinical information systems.

**[807.92(a)3] Identification of Legally Marketed Equivalent Devices
(Predicate Systems)**

Predicate System	Manufacturer	k Number
Quantitative Sentinel System	GE Marquette Medical Systems, (formerly Quantitative Medicine, Inc.) 200 Harry S. Truman Pkwy. Annapolis, MD 21401	K973608
Corometrics Spectra-Tel Telecommunications and Display System	Corometrics Medical Systems, Inc. 61 Barnes Park Road North Wallingford, CT 06492	K852608, k894958

[807.92(a)4 & 807.92(a)5] Device Description & Intended Use

The Quantitative Sentinel (QS) System is a software application that is intended for use as clinical data management system (also referred to as a clinical information system - CIS). The primary function of the system is the management of clinical data (whether manually or automatically acquired) for the purpose of providing integrated, ready and organized access to patient and/or clinical data that would normally be provided on paper records and/or separate clinical systems/devices. The QS System serves as a decision support tool as well as an electronic medical record. The QS System operates on off-the-shelf software and hardware. The device is intended for use in a hospital/clinical environment.

[807.92(a)6] Predicate Device Comparison of Technological Characteristics

Parameter	QMI's QS System Version 5.04.1	QMI's Predicate QS System (k960109)	Corometrics Spectra-Tel (k852608)
Interface HIS, physiologic monitors	Yes	Yes	Yes
Network architecture	Ethernet, Token Ring, or IBM Wireless LAN	Off-the-shelf computers and accessories	No network; modem connection
Hardware platform	Off-the-shelf computers and accessories	Off-the-shelf computers and accessories	Off-the-shelf computers and accessories
Spectra Alerts	Yes	No	Yes
Remote Access to fetal monitor patient data	Yes (via web-browser)	Yes (via WAN or modem connection)	Yes (via modem connection)

[807.92(b)1, 807.92(b)2 & 807.92(b)3] Performance Standards per the Food, Drug and Cosmetic Act

To date, no performance standards relating to devices of this type have been promulgated by the Food and Drug Administration.

[807.92(d)] Additional Information

The QS software and its environment have been extensively tested to meet its requirements and design. No clinical testing was necessary to demonstrate conformity to performance requirements.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 1999

Ms. Maria Vitug Fouts
Senior Regulatory Compliance Specialist
GE Marquette Medical Systems, Inc.
200 Harry S. Truman Parkway, Suite 220
Annapolis, MD 21401

Re: K993008
Quantitative Sentinel (QS) System, Version 5.04.1
Dated: September 7, 1999
Received: September 7, 1999
Regulatory Class: II
21 CFR§ 884.2740/Procode: 85 HGM

Dear Ms. Fouts:

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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 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 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

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

510(k) Number (if known): k993008

Device Name: Quantitative Sentinel (QS) System

Indications for Use:

The Quantitative Sentinel (QS) System's is intended for automatic patient data management. It does this by:

- (a) providing the user the ability to create and use electronic forms for entering, viewing and storing patient and facility related data (e.g. charts, forms, graphs, chalkboards, care plans, user reference manual).
- (b) interfacing with other hospital information systems and medical devices for automatic data acquisition, viewing and storage with the electronic patient record.
- (c) providing visual notification of when acquired fetal monitor heart rate values exceed the user defined limits for high and low fetal heart rate and poor signal quality.
- (d) providing Spectra Alerts capabilities for fetal monitoring (surveillance).
- (e) providing automatic computations of physiologic indexes (e.g. nutrition).
- (f) providing calculations from user defined formulas (i.e. index calculator).
- (g) providing the ability to record, with the patient record, fluid input and output information that is defined by the user.
- (h) providing the ability to export patient data to relational databases for research and Quality Assurance purposes.
- (i) providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk).
- (j) providing the ability to print (locally or remotely) patient records and QS database definition (e.g. item names)
- (k) providing the ability to review fetal monitor data (OB-Link) remotely over the internet.

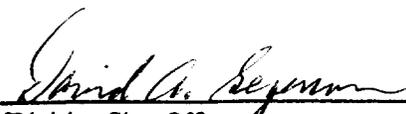
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence if CDRH, Office of Device Evaluation (ODE) _____

Prescription Use
 (Per 21 CFR 801.19)

OR

Over the Counter Use



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number k993008