

DEC 15 1999

K 990058

Exhibit 19 Summary of Safety & Effectiveness

The *QMS Mapping System™*, *Model 2000* is a computerized Cardiographic *QMS Mapping* system designed for clinical applications to allow health care providers to collect, compute, map, record and display patient diagnostic data to provide a detailed electrophysiological map of the inside of the heart. As such, *this device* is a Class II device, having Regulation Number: **21 CFR Part 870.1875**, Classification Number: **74- DQD**.

This summary is submitted in behalf of

CathData Inc.

801 York Mill Road, Suite 314

Don Mills, Ontario, Canada M3B 1X7

Voice phone number-416 383 1520

Fax phone number- 416 383 1533

this summary is submitted by:

Richard Keen

Compliance Consultants

1151 Hope Street

Stamford, Connecticut, 06907

voice phone number (203) 329 2700)

fax phone number (203) 329 2345.

This device can be **described** as QMS software which receives signals from a proprietary QMS switchbox that connects to an ancillary "basket catheter" {not part of this system} and interfaces with a qualified electrophysiology amplifier {not part of this system}. This device receives signals from the "basket catheter" and uses a computer algorithm to derive the patient mapping information.

This device **functions** by receiving signals from the "basket catheter" and uses a computer algorithm to derive the patient mapping information.

The **scientific concept** on which this device is based on is the principle that by receiving a complex configuration of electrical signals from the heart {via the "basket catheter"}, reliable data concerning the electrical properties of the heart can be derived and that data can be represented in meaningful views.

The **intended use** of this device is only upon prescription by a trained medical practitioner (who decides this device is suitable to map a patient's heart activity (to published specifications). This device is not to be offered on a non-prescription basis and will not be available to physicians having specific qualified electrophysiology amplifiers.

Exhibit 19 Summary of Safety & Effectiveness

This device is indicated for use in monomorphic, stationary atrial and ventricular arrhythmias. This device collects, records, and displays cardiac depolarization events for patients under the care of a skilled health care practitioner.

CathData Inc. has determined that the **QMS Mapping System[™], Model 2000** is substantially equivalent to the performance of an existing medical device: Integrated Mapping Software Module from Prucka Engineering, Inc. {K-902716}. The differences between these systems are incidental and not significant. Both devices use a similar technology and principles.) is a device having a similar product offering and is distributed only as a prescription device.

CathData Inc. has determined that *this device* is substantially equivalent to the predicate device and has similar technological characteristics

both systems display data on computer screens,
both systems displays patient information which relates to a unique patient;
both uses computer programming to operate and record patient data,
both use a computer algorithm to compute complex signals,

A series of non-clinical tests were conducted to verify the device is accurate and calibrated and can maintain calibration over its useful life.

The **QMS Mapping System[™], Model 2000** has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. **CathData Inc.** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:

I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.



Mr. Anthony King
Product Manager
CathData Inc.

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Don Mills, Ontario, Canada M3B 1X7
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1999

Cathdata, Inc.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K990058
OMS Mapping System, Model 2000
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: September 24, 1999
Received: October 7, 1999

Dear Mr. Keen:

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.

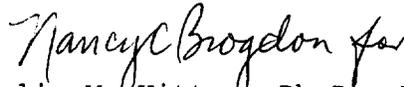
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Richard Keen

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) 594-4648. 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,



Celia M. Witten, Ph.D., M.D.
Acting Director

Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: K990058

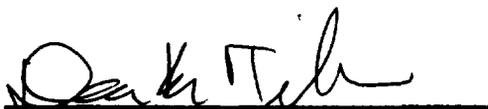
Device Name: QMS System™ Catheter Mapping System, Model 300

Indications for Use

The *QMS 3000™* is indicated for use in the storage, display, retrieval and measurement of ECG signals obtained from intracardiac catheters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K990058

Prescription Use XX
(Per 21 CFR 801.109)

OR

Over - The - Counter Use _____

(Optional Format 1-2-96)