K031169
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DEC 1 2 2003

510(k) Summary

Date prepared: April 10, 2003
Date revised: September 12, 2003

Submitter/Owner: Sierra Scientific Instruments, Inc.
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Contact person: Sean M. Curry
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San Diego, CA
Phone number: (858) 675-8200
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Proprietary name: Motility Visualization System

Common name: Gastrointestinal Motility (Electrical) System

Classification: Class II

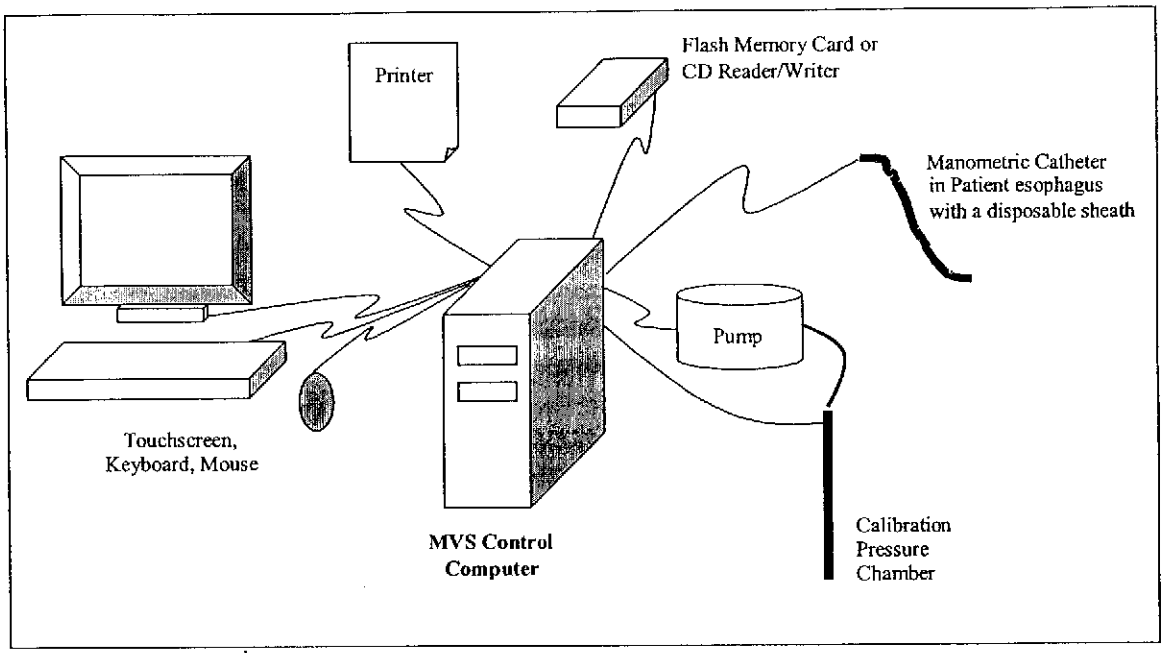
Product Code: FFX

Substantial equivalence claimed to:
1. K011472 – Medtronic, Polygraf ID and Polygram 98 software

Description:

The Motility Visualization System (MVS) obtains a high resolution mapping of pressures within tubular organs of the gastrointestinal tract. It is used in a medical clinical setting to sense the pressures along the gastrointestinal tract and stores the corresponding data. The system also provides analysis information. The real time data as well as the analysis information can be viewed by a physician for diagnostic and analysis purposes.

The system includes a catheter probe with 36 pressure sensing elements. During the clinical procedure, the catheter is inserted transnasally and pressures inside the upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), and proximal gut are measured as the patient typically swallows small amounts of water. Alternatively, the catheter may be inserted in the anus/rectum for measurement of contractile pressures in that region. Real-time data is sampled from each sensing element via the MVS interface electronics and made available to the MVS software during each sample period. The software displays the data in real-time to support the clinical procedure.



MVS System Overview

The software also supports operational utility functions such as providing the user an interface for operating the pressure calibration system. It obtains the catheter sensor and calibration chamber data during the calibration process and determines the correction factors to be used in subsequent data collection.

The MVS supports physician diagnosis and analysis by means of a playback function, which replays a stored session using previously recorded data instead of real-time data. The MVS also indicates estimated parameters such as LES location, LES resting pressure, LES relaxation, LES residual pressure, pressure inversion point (PIP) location, UES pressure, and motility metrics such as peristaltic wave amplitude, duration and velocity.

Product Functions

The primary MVS functions are:

- Calibrate the pressure sensors
- Provide user interface displays, prompts, and controls
- Collect pressure data
- Display and store collected data
- Replay stored data

Intended use:

The MVS obtains a high resolution mapping of pressures within tubular organs of the human gastrointestinal tract. These organs include the esophagus from the pharyngeal region through the stomach, the duodenum, and the anus/rectum. It is used in a medical clinical setting to sense the pressures and store the corresponding data. The system also provides analysis information. The real time data as well as the analysis information can be viewed by a physician for diagnostic and analysis purposes.

The system includes a catheter probe with 36 pressure sensing elements. During the clinical procedure, the catheter is inserted transnasally and pressure inside the pharynx, esophagus, or proximal gut (stomach/duodenum) is measured as the patient typically swallows small amounts of water. Alternatively, pressures within the anus/rectum are measured via rectal intubation. Real-time data is sampled from each sensing element via the MVS interface electronics and made available to the MVS software during each sample period. The software displays the data in real-time to support the clinical procedure.

Summary of technological characteristics:

The MVS catheter is equivalent to the Medtronic catheter which is manufactured by the same company, Konigsberg Instruments. The primary difference being the larger number of pressure sensors (typically 4-16 for the predicate device and 36 for the applicant device). The MVS system uses a proprietary signal processing scheme to minimize the number of electrical conductors.

The user interface is via touch screen display, keyboard and mouse and the use of a hard drive that allows recording and play back of the data. By providing more data, the system gives a more complete pressure data set of the esophagus. The system can also be used if there are inactive sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Sierra Scientific Instruments, Inc.
c/o Mr. Sean M. Curry
Certified Software Solutions, Inc.
16787 Bernardo Center Drive, Suite A-1
San Diego, CA 92128

Re: K031169
Trade/Device Name: Sierra Scientific Motility Visualization System (MVS)
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 FFX
Dated: September 12, 2003
Received: September 15, 2003

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to 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 Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

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

510(k) Number (if known): K031169

Device Name: Motility Visualization System

Indications for Use:

The Motility Visualization System obtains a high resolution mapping of pressures within tubular organs of the gastrointestinal tract. These organs include the esophagus from the pharyngeal region to the stomach, the proximal gut (stomach/duodenum), and the anus/rectum. It is used in a medical clinical setting to sense the pressures and store the corresponding data. The system also provides analysis information. The real time data as well as the analysis information can then be viewed by a physician for diagnostic and analysis purposes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031169