K020967

JUN 2 0 2002

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is _____.

Submitter's Name: Terumo Cardiovascular Systems Corporation
Submitter's Address: 1311 Valencia Avenue, Tustin CA 92780
Contact Person: Steve Arick
Phone Number: (734) 741-6238
FAX Number: (734) 663-5062

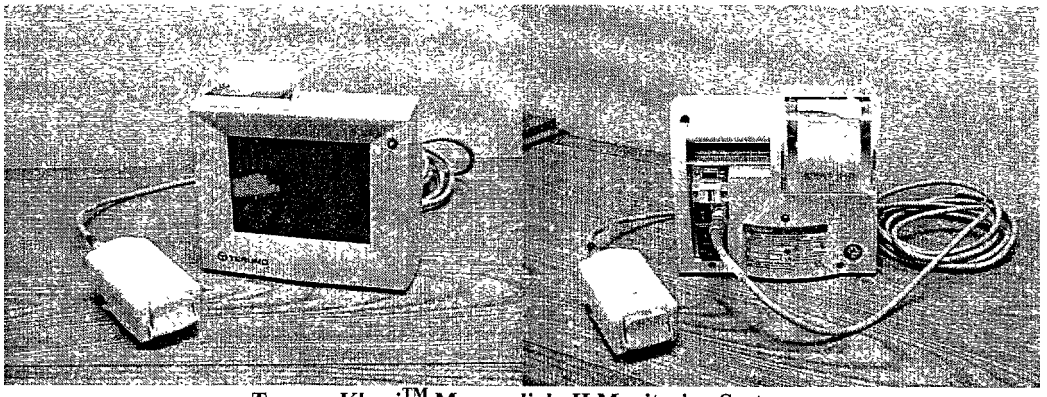
Summary Date: March 15, 2002

Device Trade Name:
Terumo Khuri™ Myocardial pH Monitoring System

Device Classification Name: CBZ 868.1170
Indwelling Blood Hydrogen Ion concentration (pH) analyzer (21 CFR ~~870.4330~~)

Predicate Devices:
K862114 Khuri Regional Tissue pH Monitor

Device Description:



Terumo Khuri™ Myocardial pH Monitoring System

The Terumo Khuri™ Myocardial pH Monitoring System (Khuri MpH system) is an AC-powered (battery support for memory retention), microprocessor-based device consisting of a monitor, sensor and interface module[1]. The myocardial pH sensor will consist of two pH measurement probe electrodes and a reference electrode for the purpose of monitoring continuous myocardial tissue pH and temperature during cardiac surgery. The system uses electrochemical technology to measure the hydrogen ion content of the myocardial tissue, and report that information via electrical cable back to the monitor, where a processing unit coverts the electrical signal into pH units for display on the monitor.

The glass pH electrode is the most common method used to obtain accurate pH measurements. Due to the nature of the glass used in the electrode, an electric potential is developed across the glass. This potential is proportional to the difference in pH between an analyte solution in contact with the exterior surface of the glass and the phosphate based internal buffering solution.

The Khuri MpH system Monitor consists of a single board computer and a dedicated circuit that contains digital circuitry to interface with the interface module[1] that connects to the sensor (pH electrodes and reference probe). The system will have an LCD flat touch screen display that will control the mode and operation of the monitor. The monitor will have a printer that will enable the user to print out case results. The monitor will be able to be mounted on a vertical pole or rest on a flat surface.

Each Khuri MpH system Sensor consists of two pH electrodes and one reference electrode. The pH electrodes are designed with a pointed tip for insertion into tissue with minimal resistance. The pH electrode consists of a closed end glass tube made from pH sensitive glass. The tube is filled with a phosphate based internal buffering solution in which a silver wire coated with silver chloride is inserted. The wire is attached to a cable, which is encased in an electrically shielded sheath and attaches to the monitor. The tip of the glass is pointed to allow easy insertion in to the myocardial tissue during use. The thermistor is a metal oxide ceramic tip, which is imbedded in the plastic surrounding the rear of the glass tube.

A reference electrode is used to complete the circuit. The reference electrode consists of an Ag/AgCl wire inserted into a plastic tube of KCl electrolyte solution. The front end of the tube is tapered to a small diameter to facilitate insertion into the tissue (usually near the sternum) during use. It is plugged with a semi-permeable material that prevents bulk leakage of fluid but maintains electrical contact with the patient during pH measurement. The wire protrudes from the sealed back end of the tube and is attached to a cable, which connects to the monitor.

The analog voltage signal from the sensor is fed into an interface module[1] that amplifies and conditions the analog signal to remove any interfering noise. The analog signal is then converted into digital information in the A to D converter. This digital signal is then fed from the interface module[1] to the monitor where a conversion algorithm, in the monitor, is used to convert digital information into pH units. The values are then displayed on the monitor screen.

Indications for Use:

The Khuri MpH system is intended for use in monitoring local tissue pH and temperature, typically during procedures in which specific tissues may be subjected to conditions which may result in ischemia, such as the myocardium, during cardiac operations. These parameters are displayed at 37°C corrected value. For documentation purposes, the integral printer provides a hard copy of displayed parameter.

Technological Characteristics:
The Khuri MpH system is identical to the technology found in the Khuri Regional Tissue pH Monitor. The Khuri MpH system is identical to its predicate device except in the following ways:

1) Placement of the thermistor for temperature measurement is now integrated in the pH measuring electrode. With the Khuri Regional Tissue pH monitor the temperature measurement was located in three separate 22-guage needle precision thermister temperature probes.

2) The Khuri MpH system Probe is intended for single-use only. The Khuri Regional Tissue pH monitor electrodes were designated to be reusable.

3) Line power: The Khuri MpH system runs off of AC line power. The Khuri Regional Tissue pH monitor was battery powered. The Khuri MpH system conforms to IEC 601-1 series.

4) The Khuri MpH system Sensor will be Gamma Radiation sterilized, where as the Khuri Regional Tissue pH Probes were Ethylene Oxide sterilized. However, both were sterilized according to the sterility assurance level of 10^{-6} therefore, there is no impact on safety and effectiveness.

Nonclinical Performance:
The performance characteristics of the Khuri MpH system were exhaustively tested and compared with the performance characteristics of the predicate device. All new and existing performance characteristics of the Khuri MpH system have been validated.

Conclusions from Nonclinical Tests:
The Khuri MpH system performs as intended according to its performance specifications. The Khuri MpH system is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2002

Terumo Cardiovascular Systems Corporation
c/o Mr. Steve Arick
Regulatory Affairs Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K020967
Trade Name: Terumo Khuri™ Myocardial pH Monitoring System
Regulation Number: 21 CFR 868.1170
Regulation Name: Analyzer, Ion Hydrogen-Ion, (pH) Blood, Phase Indwelling
Regulatory Class: Class II (two)
Product Code: CBZ
Dated: March 15, 2002
Received: March 25, 2002

Dear Mr. Arick:

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 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 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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). 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020967

2.4 ODE Form, Indications for Use Statement

510(k) Number (if known): K020967

Device Name: Terumo Khuri™ Myocardial pH Monitoring System

Indications for Use:

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020967