K043075

Tenacore Holdings, Inc

647 East Young Street – Santa Ana, CA 92705 Ph: 714-444-4643 Fx: 714-549-7835

Section 9: 510(k) Summary

AUG 1 8 2005

Contact Person: Brand Caso
Director Product Development
Tenacore Holdings, Inc
647 East Young Street
Santa Ana, CA 92705

Date Prepared: March 1, 2004

Product Classification: Product Classification. Class 11-Transducers for use with perinatal monitoring systems as accessories as described in Title 21. Part 884, Subpart C, Classification *85* HGL, Regulation number Obstetrical Ultrasonic Transducer and Accessories and in Title 21, Part 884, Subpart C, Classification *#85* HFM, Regulation number 884.2720 External Uterine Contraction Monitor and Accessories

Trade Name: Tenacore Transducers for Fetal Ultrasonic and Tokodynamometer Monitoring.

Common Name: Transducers for Fetal Ultrasonic and Tokodynamometer Monitoring

Predicate devices:
a. Corometrics 116 (5700 & 2260), 510 (k) # K891S95 by GE Marquette Medical Systems
b. Epic's transducer, 510(k) #992811 by Epic Medical Equipment Services.

Description: Tenacore Holdings, Inc. Transducers for Fetal Ultrasound and Tokodynamometer Monitoring are direct replacements for similar transducers manufactured by GE Marquette Medical Systems and Epic Medical Equipment Services. A Transducer employing ultrasound Doppler Shift Technology is used for the detection of Fetal Heart Rate during labor and a Tokodynamometer Transducer, which actually is a strain gauge, is used to evaluate and measure the duration, frequency, and relative pressure of uterine contractions during labor.

Intended Use: Tenacore Transducers for Fetal Ultrasound and Tokodynamometer Monitoring arc intended to be used only as direct replacement accessories for appropriate Perinatal Monitoring Systems that display the graphical relationship between labor and fetal heart rate.

Performance Standards: Tenacore Holdings, Inc has declared to conform to consensus performance standards concerning Electrical Electromagnetic Compatibility / Mechanical / Efficacy / Safety and Biocompatibility aspects of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2005

Mr. Brand Caso
Director of Product Development
Tenacore Holdings, Inc.
647 East Young St.
SANTA ANA CA 92705

Re: K043075
Trade/Device Name: Transducers for use with Perinatal Monitoring Systems and Accessories
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: July 1, 2005
Received: July 18, 2005

Dear Mr. Caso:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K043075/S2

Device Name: Transducers for use with perinatal monitoring systems as accessories

Indications For Use:

These transducers are intended to be used as replacement accessories for Hewlett Packard and Corometrics fetal monitors. These transducers measure fetal heart rate or uterine contractions in the gravid patient.

Tenacore Transducer	Compatible Monitors
Model TFH102	For use with Hewlett Packard 1350 Series Fetal Monitors
Model TFC102	For use with Corometrics Model 115, 116, 118, 120, and 150 Series Fetal Monitors
Model TFH101	For use with Hewlett Packard 1350 Series Fetal Monitors
Model TFC101	For use with Corometrics Model 115, 116, 118, 120, and 150 Series Fetal Monitors

Prescription required.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043075