

DEC 11 1998

**510(k) SUMMARY: Corometrics Model 5700 and 2264 Watertight Transducer**

Prepared: 7/29/98

**[ 807.92(a)1 ] Contact Information**

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Regulatory Affairs Manager

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**[ 807.92(a)2 ] Device Name and Classification**

The proprietary names of the devices to be introduced into interstate commerce are the Corometrics Model 5700 & 2264 Series Watertight Transducers. Common name includes: Ultrasound and Tokodynamometer Transducer.

Current classifications that applies to these devices are: 21 CFR part 888.2720 – “External Uterine Contraction Monitor and Accessories,” Class II; and 21 CFR part 888.2740 “Perinatal Monitoring System and Accessories,” Class II.

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

Predicate System	Manufacturer	K Number	Class
Model 5700 US Transducer	Corometrics Medical Systems, Inc.	k891595	II
M1356A US Watertight Transducer	Hewlett Packard	K942887	II

Predicate System	Manufacturer	K Number	Class
Model 2260 Toco Transducer	Corometrics Medical Systems, Inc.	k891595	II
M1355A Toco Watertight Transducer	Hewlett Packard	k942887	II

**510(k) SUMMARY Continued:****[ 807.92(a)4 & 807.92(a)5 ] Device Description & Intended Use**

The Model 5700 and 2264 Series Non-Invasive Watertight Transducers are intended as accessories to Corometrics' Fetal and Fetal/Maternal Monitors. The Model 5700 Series Transducer provides for the detection of fetal heart rate and the Model 2264 Series Transducer provides for the detection of uterine activity.

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

Mode	Model 5700 US	Model 5700 Watertight US	HP M1356A Watertight US
Indications for Use	FHR	FHR	FHR
Watertight	No	Yes	Yes
Pulsed Doppler	Yes	Yes	Yes
No. of Crystals	9	9	7
Water Environment Application Use	No	Yes	Yes

FHR: Fetal Heart Rate

Mode	Model 2260 Toco	Model 2264 Watertight Toco	HP M1355A Watertight Toco
Indications for Use	UA	UA	UA
Watertight	No	Yes	Yes
Water Environment Application Use	No	Yes	Yes

UA: Uterine Activity

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

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

**[ 807.92(d) ] Additional Information**

The Corometrics Model 5700 and 2264 Series Watertight Transducers have been extensively tested to meet their requirements and design.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Richard Cehovsky  
Manager, Regulatory Affairs  
Corometrics Medical Systems, Inc.  
61 Barnes Park Road North  
P.O. Box 333  
Wallingford, CN 06492Re: K982651  
Corometrics Model 5700 and 2264 Watertight  
Transducer  
Dated: November 5, 1998  
Received: November 6, 1998  
Regulatory Class: II  
21 CFR 884.2660/Procode: 85 HEL  
21 CFR 884.2720/Procode: 85 HFM

Dear Mr. Cehovsky:

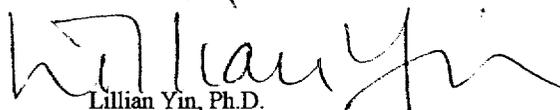
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,

Lillian Yin, Ph.D.  
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): \_\_\_\_\_ \*

Device Name: Model 5700 & 2264 Series Watertight Transducer

Indications for Use:

Use of the Model 5700 and 2264 Series Non-Invasive Watertight Transducers are indicated as accessories to Corometrics Fetal and Fetal/Maternal Monitors. The Model 5700 Watertight Transducer provides for the **detection of fetal heart rate** and the Model 2264 Watertight Transducer provides for **the detection of uterine activity**. Both transducers are intended to be used in either water or non-water environments. When used in water environment applications both transducers are intended to be directly connected to telemetry and not directly connected to a Fetal or Fetal /Maternal monitor or any AC powered monitoring devices. Labeling and labels, on the transducers themselves, instruct the care provider to directly connect the transducers to a telemetry system when the devices are exposed to a water environment.

\* To be assigned by FDA upon receipt of 510(k) submission.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.19)

OR

Over the Counter Use \_\_\_\_\_

Optional Format 1-2-96

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number           K952651          

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