Ventrex, inc.
Vision in Design and Manufacturing

JUL 12 2006

510(K) SUMMARY
FeatherLite™Aqua Tocodynamometer

Date:	April 10, 2006
Manufacturer:	Ventrex Inc. 3007 Bunsen Avenue, Suite K Ventura,CA 93003 FDA Registration # 2029412
Owner/Operator:	Ventrex Inc. 3007 Bunsen Avenue, Suite K Ventura,CA 93003
Contact Person:	George Austria Director of Quality Assurance Ventrex, Inc. 3007 Bunsen Avenue, Suite K Ventura,CA 93003
Device Trade Name:	FeatherLite Aqua™Tocodynamometer
Common Name:	Toco
Classification Name:	Class II, 85HFM, External Uterine Contraction Monitor and Accessories
Regulatory Reference:	884.2720
Predicate Device:	FeatherLite™Tocodynamometer under 510k# K013477 and Corometrics 2264 under K982651.
Description and Intended Use:	The FeatherLite Aqua™ tocodynamometer (toco) is intended for use in conjunction with telemetry systems for standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods in a clinical setting. The fetal monitor is not intended for home monitoring or pre-term labor. It can be used in both dry and fully submerged environments. It

is held in place on the surface of the abdomen using an elastic belt. It is sold non-sterile and is intended for single use only.

Summary of Similarities and Differences:

Similarities:
Ventrex FeatherLite™ Toco under 510(k) K013477 (Predicate Device) and FeatherLite Aqua™ Toco (New Device):

- Both are used in conjunction with fetal monitors for evaluation of external uterine activity.
- Same performance characteristics.
- Both use a flexible nipple and silicone gel to transmit the changes in uterine wall muscle tone to the strain gauge pressure sensor housed inside.
- The sensor for both FeatherLite™ and FeatherLite Aqua™ are the same. (resistive type)
- The housing materials are the same . (molded from rigid thermoplastics)
- The same attachment methods.
- Both devices cannot be serviced.
- Both use an adaptor to connect the universal connector of the cable to the specific fetal monitor.

Differences:

- Atmospheric pressure referencing on the predicate device is achieved through a vent hole on top of the housing while the venting on new device is achieved through a lumen in the cable.
- The FeatherLite Aqua™ Toco may be used in a water environment.
- The cover is sealed to the housing using a water proof sealant for the new device to prevent water from entering.
- The adapter includes a digital filter to minimize unwanted noise without interfering with performance.
- The adapter has a switch to allow the user to increase the toco gain for more effective monitoring of obese patients.
- The FeatherLite Aqua™ is intended for single use only.
- The FeatherLite Aqua™ shall ONLY be used with telemetry units.

Similarities: GE/Corometrics 2264 Tocodynamometer under K982651.

- Same principle of sensing the change in muscle tone of the uterus as it contracts by firmly holding a nipple-like appendage against the abdominal wall utilizing an elastic belt as the holding means.

- Both devices can be used in either water or non-water environments.
- Both devices require a telemetry unit when used as a submersible device.

Differences:

- Monitor connector is hard wired onto the cable of the predicate device.
- Predicate device has an electronic filtering circuitry in the toco. New device has in the adaptor.

CONCLUSION:

- The proposed FeatherLite Aqua™ (New Device) is comparable to its predicate devices in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 12 2006

Mr. George Austria
Director of Quality Assurance
Ventrex, Inc.
3007 Bunsen Avenue, Suite K
VENTURA CA 93003

Re: K061044
Trade/Device Name: FeatherLite Aqua™ Tocodynamometer
Regulation Number: 21 CFR 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: HFM
Dated: April 10, 2006
Received: April 17, 2006

Dear Mr. Austria:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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 Statement

Applicant: Ventrex, Inc.

510(k) Number: K061044

Device Name: FeatherLite Aqua™

Indication For Use

The FeatherLite Aqua™Toco dynamometer is intended for use in conjunction with telemetry systems for standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods. Is should only be used in a clinical setting. It may be fully submerged in water for water birthing or monitoring in a whirlpool. **Caution: FeatherLite Aqua™Toco is not intended for home monitoring of pre-term labor.**

Placement over the fundal area of the uterus to the left or right of the midline is suitable for most patients, It is held on the surface of the abdomen using a standard button hole or Velcro™ type belt.

The product is supplied non-sterile and is intended for single use only.

(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. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061044