Ventrex, inc.
Vision in Design and Manufacturing

JAN 17 2002

Section E
510 (k) Summary

Applicant Information

Submitter's Name:	Robert Guthrie
Address:	3007 Bunsen Avenue, Suite K, Ventura, California 93003
Telephone/Fax Numbers:	805-658-2984 x 100 or x 109 / 805-658-6720
Contact Person:	Robert Guthrie or Doug Divine
Date Summary Prepared:	October 11, 2001

Device Information

Trade Name of Device:	**Toco Lite**
Common Name:	Tocodynamometer (Toco) or Toco transducer
Classification Name:	External Uterine Contraction Monitor and Accessories (per 21 CFR section 884.2720/Procode: 85HFM)

Predicate Device Information

Predicate Device/s To Which Equivalence is Claimed: ***Agilent Technologies (Hewlett Packard) tocodynamometer model M1355A***

GE (Corometrics) tocodynamometer model 2260

Device General Description and Intended Use

The FeatherLite Toco is a tocodynamometer (toco) intended for use in conjunction with standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods in a clinical setting. The FeatherLite Toco is not intended for home monitoring of pre-term labor. 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 or limited reuse.

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Device Specific Description

The FeatherLite Toco is generally rectangular in shape with a domed sensor body and nipple-like appendage. It includes a belt to hold it on the patient. The device is lower profile and significantly lighter than standard tocos.

The rectangular base and dome sensor body are molded from thermoplastic. The sensing nipple is formed from a flexible polymer. The sensor is a strain gauge. The cable is a jacketed array of four individually insulated wires. The belt is an elastic nylon webbing.

Technological Characteristics vs. Predicate Devices

Differences From Predicate Devices (Predicate device Agilent/Hewlett Packard M1355A tocodynamometer - 510 (k) most likely as an accessory to an Agilent/HP fetal monitor. Product is described in K900480: Predicate device Corometrics 2260 tocodynamometer - 510 (k) most likely as an accessory to a Corometrics fetal monitor. Product is described in K843385.

Performance Characteristics for Determination of Substantial Equivalence

The FeatherLite Toco performance was tested under both non-clinical and clinical conditions to determine substantial equivalence to the predicate devices.

Summary Comparison vs. Predicate Devices

	New Device	Predicate Devices	
Topic	**FeatherLite Toco**	**Agilent / HP**	**GE / Corometrics**
Intended use	Senses uterine activity	Same	Same
Indications for use	Used in conjunction with fetal monitors for evaluation of external uterine activity	Same	Same
Target patient population	Pregnant patients	Same	Same
Design	Sensing nipple attached to strain gauge	Same	Sensing diaphragm attached to strain gauge
Materials	Thermal plastics and polymers, vinyl clad cable, wheat stone bridge sensor	Same	Same
Performance	Please see "Performance" in section I	Same	Same
Sterility	Non-sterile	Same	Same

Biocompatibility	Materials in direct skin contact USPC VI	Unknown	Unknown
Patient Safety	Please see "Safety" in section I	Unknown	Unknown
Anatomical sites	Surface of abdomen over fundal area of uterus	Same	Same
Human factors	Very low profile, small, light weight	Bulky, heavy	Bulky, heavy
Energy used	Low voltage supplied by monitor	Same	Same
Compatibility with environment/other devices	MRI and EMI interference not applicable due to indications for use	Same	Same
Standards met	None established	Same	Same
Patient attachment	Elastic belt	Same	Same
Cable Length	8 feet	8 feet	8 feet
Accessories	Replacement belts, monitor adaptors	Replacement belts	Replacement belts

Performance Conclusions

The clinical and non-clinical testing supports the substantial equivalence of the FeatherLite Toco to the predicate devices. All devices employ the same theory of operation and basic design elements. The performance specifications are comparable. The data sensed by the FeatherLite Toco in clinical testing was also quite comparable to that measured by the predicate device despite being positioned in a sub-optimal location.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Mr. Robert Guthrie
General Manager
Ventrex, Inc.
3007 Bunsen Avenue, Unit K
VENTURA CA 93003-7633

Re: K013477
Trade/Device Name: Featherlite Toco
Regulation Number: 21 CFR 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product Code: 85 HFM
Dated: October 16, 2001
Received: October 19, 2001

Dear Mr. Guthrie:

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 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:

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" (21 CFR 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,

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

Section D

Statement of Indications for Use

Applicant: *Ventrex, inc.*

510(k) Number: K013477

Device Name: ***FeatherLite Toco*** **model TD-01**

INDICATIONS FOR USE

The *FeatherLite Toco* tocodynamometer is intended for use in conjunction with standard fetal monitors for the evaluation of external uterine activity during antepartum and intrapartum periods. It should only be used in a clinical setting. **Caution: The *FeatherLite 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 in place on the surface of the abdomen using the attached elastic belt.

The product is supplied non-sterile and is intended for single use or limited reuse following appropriate cleaning per hospital protocol.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013477

Prescription Use ✓