K982800

SEP 22 1998

Ecton

Suite 100
110 West Butler Avenue
Ambler, Pennsylvania 19002
215 283-1800
Fax 215 283-1809

4.2
510(k) Summary of Safety and Effectiveness
21CFR 807.92

1) Submitter's Name/Address/Phone/Contact Person:

Christopher B. Knell
Director of Engineering
Ecton, Inc.
Suite 100
110 West Butler Avenue
Ambler, Pennsylvania 19002
215 283 1800π
215 283 1809 (fax)
c.knell@ieee.com (email)

Date Summary Was Prepared: June 6, 1998

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:

Diagnostic Ultrasound System

Proprietary Name:

Ecton Lynx Ultrasound System

Classification Names:

The FDA has classified Ultrasound Imaging Systems as Class II in 21 CFR:

FR #/ Product Code

892.1550/90IYN Ultrasonic Pulsed Doppler Imaging System
892.1560/90IYO Ultrasonic Pulsed Echo Imaging System
892.1570/ 90ITX Diagnostic Ultrasound Transducer

3) Predicate Devices:

In this 510(k) submission, the legally marketed devices to which we claim substantial equivalence are:

Manufacturer	Product	K Number
Hewlett Packard Co.	Sonos 2500 Ultrasound System	K934041
ATL, Inc.	HDI 3000 Ultrasound System	K935009
Kontron	Mipron Image Processing System	K891689
Acuson Corp.	Sequoia: Harmonic Imaging with Contrast	K97376
Hewlett Packard Co.	Sonos 2500: Harmonic Imaging	K964309

4) Device Description

The Ecton Lynx Ultrasound System is a general purpose and cardiac diagnostic ultrasound system. It is a highly portable digital system. Its function is to transmit and acquire ultrasound image data and display it on a monitor. The system operates in 2D, M-Mode, Color Flow Doppler, Doppler Tissue Imaging, and Continuous Wave Doppler modes. The Lynx provides the operator with the ability to perform measurements and calculations on images using established clinical formulae. The Lynx complies with the Track 3 Output Display Standard, providing an automatic display of Mechanical Index and Thermal Index.

The Ecton Lynx is designed to operate linear and linear phased array transducers (probes). Four probes are included in the current submission: a 2.5MHz external probe, a 5.0MHz external probe, a 5.0MHz biplane transesophageal probe, and a 5.0MHz monoplane transesophageal probe. The transesophageal probes contain a temperature sensing device that is used to limit the surface temperature to 43 degrees C.

The Ecton Lynx includes a stress echocardiography software package that utilizes conventional techniques to capture and format images for stress echocardiography

studies. The system provides digital output of images in conformance with the DICOM standard. The Lynx does not utilize lossy compression techniques in image storage or transmission.

The Ecton Lynx has been designed to meet or exceed the following safety standards:

IEC601-1: International Electrotechnical Commission, Medical Electrical Equipment

C22.2 No. 601.1: Canadian Standards Association, Medical Electrical Equipment

IEC 601-1-2 International Electrotechnical Commission, Collateral Standard: Electromagnetic Compatibility

5) Indications for Use / Intended Use

The Ecton Lynx is intended for adult and pediatric cardiac, intraoperative cardiac, peripheral vascular, abdominal, fetal, pediatric and neonatal cephalic imaging. The Lynx is not intended for ophthalmic, intraoperative neuralgic, or adult cephalic imaging. The system may be used with or without legally marketed ultrasound contrast agents. The system makes no claims regarding the use of ultrasonic contrast agents but provides harmonic imaging capability, receiving echoes at a multiple of the transmit signal and providing electrocardiographic gating that may be used in conjunction with contrast agents. Indications for use include:

· Adult and pediatric cardiac studies using external probes.

· Intraoperative adult and pediatric (size permitting) cardiac studies using a transesophageal probe.

· Intraoperative adult and cardiac studies using a sheathed "external" probe.

· Adult and pediatric (size permitting) cardiac studies using a transesophageal probe.

· Abdominal studies.

· Pediatric studies to detect abnormalities in organs, superficial or bony structures.

· Neonatal cephalic studies.

· Peripheral vascular studies including cerebrovasculature and extremeties.

· Fetal studies.

6) Technological Characteristics

The Ecton Lynx operates in a manner that is identical to the predicate devices for each scanning mode: piezoelectric material in the transducer is used as an ultrasound generator to transmit sound waves into the body. Reflected sound waves are received by the transducer and converted into electrical signals that are processed and displayed as 2D (B-Mode) or M-Mode images. Doppler shift techniques are used to process signals and display them as 2D color flow velocity maps Doppler Tissue Imaging, or continuous wave spectral Doppler.

The Lynx conforms to the Standard for Real-Time Display of Thermal and Mechanical Acoustic Indices on Diagnostic Ultrasound Equipment (AIUM/NEMA 1996) for the on-screen display of mechanical and thermal indices. This feature provides the user with information on potential thermal and cavitation bioeffect mechanisms. A user education program provides information instructing users on machine settings and scanning techniques that allow for examinations to be conducted in accordance with the ALARA (as low as reasonably achievable) principle.

The acoustic output limits of the Lynx are the same as predicate Track 3 devices:

Acoustic Output Limits*

ISPTA	720 mW/cm^2	(Maximum)
TIS/TIB/TIC	0.1 - 4.0	(Range)
Mechanical Index	1.9	(Maximum)
ISPPA	0-700 W/cm^2	(Range)

*the Lynx is not intended for ophthalmic uses.

7) Potential Adverse Affects

This device has no known adverse affects on human health when used in the prescribed manner for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Ecton, Inc.
c/o Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K982800
Ecton Lynx Ultrasound System
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: September 10, 1998
Received: September 11, 1998

Dear Mr. Mosenkis:

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 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Ecton Lynx Ultrasound System, as described in your premarket notification:

Transducer Model Number

2.7 MHz External Transducer
5.0 MHz External Transducer
5.0 MHz Biplane Transesophageal Transducer
5.0 MHz Monoplane Transesophageal Transducer

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert A. Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Feigal

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

Enclosures

4.2 / 4.3

Indications for Use Form

Ecton Lynx Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

System Indications

Clinical Application	B	M	CWD	Color Doppler	Amplitude Doppler (Doppler Tissue Imaging)	Other (specify) Harmonic Imaging
Fetal	•	•	•	•	•	•
Abdominal	•	•	•	•	•	•
Intraoperative-Cardiac	•	•	•	•	•	•
Pediatric	•	•	•	•	•	•
Neonatal Cephalic	•	•	•	•	•	•
Cardiac (Adult)	•	•	•	•	•	•
Cardiac (Pediatric)	•	•	•	•	•	•
Transesophageal	•	•	•	•	•	•
Peripheral Vascular	•	•	•	•	•	•

Additional Comment: The Ecton Lynx does not provide Combined Modes (where more than one scanning mode is active simultaneously.)

New Submission: All Indications New **4.3 p 1**

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K982800

4.2 / 4.3

Indications for Use Form

Ecton Lynx Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

2.7 MHz External Transducer

Clinical Application	B	M	CWD	Color Doppler	Amplitude Doppler (Doppler Tissue Imaging)	Other (specify) Harmonic Imaging
Fetal	•	•	•	•	•	•
Abdominal	•	•	•	•	•	•
Intraoperative-Cardiac	•	•	•	•	•	•
Pediatric	•	•	•	•	•	•
Cardiac (Adult)	•	•	•	•	•	•
Cardiac (Pediatric)	•	•	•	•	•	•
Peripheral Vascular	•	•	•	•	•	•

Additional Comment: The Ecton Lynx does not provide Combined Modes (where more than one scanning mode is active simultaneously.)

New Submission: All Indications New **4.3 p 2**

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982800

4.2 / 4.3

Indications for Use Form

Ecton Lynx Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

5.0 MHz External Transducer

Clinical Application	B	M	CWD	Color Doppler	Amplitude Doppler (Doppler Tissue Imaging)	Other (specify) Harmonic Imaging
Fetal	•	•	•	•	•	•
Abdominal	•	•	•	•	•	•
Intraoperative-Cardiac	•	•	•	•	•	•
Pediatric	•	•	•	•	•	•
Neonatal Cephalic	•	•	•	•	•	•
Cardiac (Adult)	•	•	•	•	•	•
Cardiac (Pediatric)	•	•	•	•	•	•
Transesophageal	•	•	•	•	•	•
Peripheral Vascular	•	•	•	•	•	•

Additional Comment: The Ecton Lynx does not provide Combined Modes (where more than one scanning mode is active simultaneously.)

New Submission: All Indications New **4.3 p 3**

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982800

4.2 / 4.3

Indications for Use Form

Ecton Lynx Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

5.0 MHz Biplane Transesophageal Transducer

Clinical Application	B	M	CWD	Color Doppler	Amplitude Doppler (Doppler Tissue Imaging)	Other (specify) Harmonic Imaging
Intraoperative-Cardiac	•	•	•	•	•	•
Cardiac (Adult)	•	•	•	•	•	•
Cardiac (Pediatric)	•	•	•	•	•	•
Transesophageal	•	•	•	•	•	•

Additional Comments: Pediatric studies are dependent upon patient size. The Ecton Lynx does not provide Combined Modes (where more than one scanning mode is active simultaneously.)

New Submission: All Indications New **4.3 p 4**

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982800

4.2 / 4.3

Indications for Use Form

Ecton Lynx Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

5.0 MHz Monoplane Transesophageal Transducer

Clinical Application	B	M	CWD	Color Doppler	Amplitude Doppler (Doppler Tissue Imaging)	Other (specify) Harmonic Imaging
Intraoperative-Cardiac	•	•	•	•	•	•
Cardiac (Adult)	•	•	•	•	•	•
Cardiac (Pediatric)	•	•	•	•	•	•
Transesophageal	•	•	•	•	•	•

Additional Comments: Pediatric studies are dependent upon patient size. The Ecton Lynx does not provide Combined Modes (where more than one scanning mode is active simultaneously.)

New Submission: All Indications New 4.3 p 5

Prescription Use (Per 21 CFR 801.109)

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