JUL 16 1998

K981406

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) Accessory
Common/Usual Name:	Magnetic Resonance Imaging Coil Cover/Sheath
Proprietary Name:	Cervix Coil Latex Sheath
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Cervix Coil Latex Sheath allows use of the coil in MR scanning procedures for endocavitary exams of the cervix while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and health care worker during reuse of the coil. The latex coil cover is furnished as a non-sterile, single use (patient/procedure), disposable device.

3. Device Description

The Cervix Coil Latex Sheath has been specifically designed to fit over the Picker Hammersmith Endocavitary Cervix Coil. The sheath has an extension on the closed end that can be depressed into the center of the coil. This allows placement of the cervix within the MR coil ring without interference from the sheath. This disposable sheath prevents transfer of microorganisms, body fluids, and particulate material during reuse of the coil.

4. Safety and Effectiveness

This sheath is substantially equivalent in safety and effectiveness to the CIVCO Latex Ultrasound Transducer Covers. The following table has been provided to demonstrate this substantial equivalence.

Substantial Equivalence Chart

Parameter	Cervix Coil Latex Sheath	Predicate Device CIVCO Latex Ultrasound Transducer Cover (K970515)
Design	One-piece, open on one end, closed on the other end with dimensional configurations to accommodate the Hammersmith Endocavitary Cervix Coil. Cover is externally applied to the MR coil.	One-piece, open on one end, closed on the other end with various dimensional configurations necessary to accommodate differences in ultrasound geometries. Covers are externally applied to ultrasound transducer.
Material	Same.	Natural rubber latex. Formulation conforms with the FDA regulation 21 CFR, Section 177.2600 and manufactured according to cGMP.
Manufacturing	Same.	• Dip-molding. • Packaging in class 10,000 clean room.
Safety	Same.	Testing has demonstrated that the materials / devices are: • non-toxic. • non-sensitizing. • non-irritating. • non-hemolytic. • non-pyrogenic.
Effectiveness	Same.	Experience and testing has shown that the materials: • have sufficient physical and material properties (i.e. strength and elasticity) for the intended application. • are an effective barrier to the prevention of microbial migration.

Parameter	Cervix Coil Latex Sheath	Predicate Device CIVCO Latex Ultrasound Transducer Cover (K970515)
Intended Use / Indications for Use	The Cervix Coil Latex Sheath allows use of the coil in MR scanning procedures for endocavitary exams of the cervix while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and health care worker during reuse of the coil. The latex coil cover is furnished as a non-sterile, single use (patient/procedure), disposable device.	Protective cover or sheath placed over diagnostic ultrasound transducer / probe / scanhead instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavitary, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and health care worker during reuse of the transducer (both sterile and non-sterile covers). The cover also provides a means for maintenance of a sterile field (sterile covers only). CIVCO Latex Transducer Covers are furnished sterile & non-sterile; single use patient / procedure, disposable.
Device body Contact Category	Same.	• surface devices, intact skin / mucosal membranes / breached surfaces, limited contact duration (< 24 hours). • external communicating devices, blood path indirect / tissue communicating, limited contact duration (< 24 hours)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1998

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Cleveland, OH 44143

Re: K981406
Cervix Coil Latex Sheath
Dated: April 15, 1998
Received: April 20, 1998
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Keeler:

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): K981406

Device Name: Cervix Coil Latex Sheath

Indications for Use:

The Cervix Coil Latex Sheath allows use of the coil in MR scanning procedures for endocavitary exams of the cervix while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the coil. The latex coil cover is furnished as a non-sterile, single use (patient/procedure), disposable device.

(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, ENT,
and Radiological Devices
510(k) Number K981406

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)