K98 1410

JUN 30 1998

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

## 1. General Information

| | |
|---|---|
| Classification: | Class II<br>Magnetic Resonance Imaging (MRI) Accessory |
| Common/Usual Name: | Magnetic Resonance Imaging (MRI) Coil |
| Proprietary Name: | Hammersmith Endocavitary Coils |
| Establishment Registration: | Picker International, Inc.<br>World Headquarters<br>595 Miner Road<br>Highland Heights, Ohio 44143<br>FDA Owner Number: #1580240<br>FDA Registration Number: #1525965 |
| Performance Standards: | Not Applicable |

## 2. Intended Uses

The Hammersmith Endocavitary Coils do not change the intended use of the Picker MR system with which they are used.

Picker MR systems are intended for use as NMR devices that produce images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

The Hammersmith Endocavitary Coils are indicated for use in the following anatomic regions and with the designated nuclei:

| | |
|---|---|
| Anatomic Regions: | The Anus or Prostate by insertion into the rectum, and the Cervix by insertion into the vagina |
| Nuclei Excited: | Hydrogen |

## 3. Device Description

These three separate receive-only coils are for imaging the anus, prostate and cervix. The coils are designed to be inserted in either the rectum or vagina before imaging. The Hammersmith Endocavitary Coils are similar to the Philips Endo-Cavitary Coil in that they are reusable. However, unlike the Philips Endo-cavitary MRI Coil, they are rigid structures that do not contain an inflatable latex balloon. This difference in the design eliminates the need for limiting the number of times the Hammersmith Coils can be used, allows for fixed tuning and matching, and reduces the image artifacts due to susceptibility effects from air. Instead, the shape and dimensions of the Hammersmith Endocavitary Coils are similar to ultrasound probes used in endocavitary applications.

## 4. Safety and Effectiveness

The Picker Hammersmith Endocavitary Coils are substantially equivalent in safety and effectiveness to the Philips Endo-Cavitary MRI Coil. The following chart has been compiled to demonstrate the substantial equivalence of these devices.

| **Parameter** | **Hammersmith Endocavitary Coils** | **Predicate Device: Philips Endo-Cavitary MRI Coil (K930193)** |
|---|---|---|
| Compatible MRI Systems | Picker Edge, Vista, Asset, Eclipse, Polaris and Apollo. | Philips Gyroscan ACS Series II and Gyroscan T5 series II systems. |
| Mode of Operation | Receive-Only. | Receive-Only. |
| Antenna Configuration | Linear. | Linear. |
| Tuning/Impedance Matching | Fixed tuning and matching. Factory set. | Tuned for each patient. |
| Method of Decoupling | Active diode decoupling. | Decoupling diode switch |
| Coil Enclosure | Rigid Acrylonitrile resin. | Flexible coil loop inside a non-permeable latex balloon. |
| Coil Stabilization | External immobilization positioning device. | Inflate balloon on coil with luer-lock syringe. |
| Number of Receive Channels | One. | One. |

| Parameter | Hammersmith Endocavitary Coils | Predicate Device: Philips Endo-Cavitary MRI Coil (K930193) |
|---|---|---|
| Cleaning and Disinfection Method | Cleaning: MetriZyme detergent.<br>Disinfectant: Cidex Dip.<br>Covered with sheath. | Cleaning: Detergent.<br>Disinfectant: Cidex Dip.<br>Covered with sheath. |
| Use Limits | None. | Used up to 50 times within one year of manufacturing. |
| Indications for use | Anus or Prostate by insertion into the rectum and Cervix by insertion into the vagina. | Prostate or Uterus by insertion into the rectum. |
| Contraindications | Any exclusion for a normal digital examination. | Severe hemorrhoids, recent surgery in the area of the rectum, inflammatory bowel disease, Crohn's disease and any exclusion for normal endorectal examinations. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Elaine K. Keeler, Ph.D.
Manager, MR Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143

Re: K981410
Hammersmith Endocavitary Coils
Dated: April 17, 1998
Received: April 20, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS/90 LNH

Dear Dr. 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):** K98 1410

**Device Name:** Hammersmith Endocavitary Coils

**Indications for Use:**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981410

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