MAY 13 1998

K971374
P121

510(k) SUMMARY
GREATBATCH SCIENTIFIC MR COMPATIBLE HYSTEROSCOPE

Submitter Name:	Greatbatch Scientific Division of Wilson Greatbatch Ltd.
Submitter Address:	4100 Barton Road Clarence, New York 14031
Contact Person:	Gary J. Sfeir, RAC
Phone Number:	716.759.5277
Facsimile Number:	716.759.5280
Date Prepared:	29 August, 1997
Device Trade Name:	Greatbatch Scientific MR Compatible Hysteroscope
Device Common Name:	Hysteroscopes
Classification Name:	Hysteroscopes
Predicate Devices:	Optus, Inc. Hysteroscopes and Accessories
Device Description:	The Greatbatch Scientific MR Compatible Hysteroscopes are available in standard and autoclavable 2.0mm and 4.0mm outer diameters with 0° and 30° viewing angles.
Intended Use:	Used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.
Device Technological Characteristics and Comparison to Predicate Devices(s):	The device technological characteristics are similar in design to that of the predicate device.
Performance Data:	The device was tested for MR Compatibility and was found to be acceptable for use in a shielded 1.5 Tesla magnet.
Conclusion:	The Greatbatch Scientific MR Compatible Hysteroscope as designed can be used in a MR or an interventional MR environment not to exceed a shielded 1.5 Tesla magnet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

Gary J. Sfeir, RAC
Director, Regulatory Affairs
Greatbatch Scientific
4100 Barton Road
Clarence, NY 14031

Re: K971374
Greatbatch Scientific MR Compatible Hysteroscope
Dated: April 16, 1998
Received: April 17, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85 HIH

Dear Mr. Sfeir:

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

SECTION 4

INDICATIONS FOR USE

510 (k) Number (if known): K971374

Device Name: Greatbatch Scientific MR Compatible Hysteroscope

Indications For Use:

The Greatbatch Scientific MR Compatible Hysteroscope is used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

(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

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971374

(OPTIONAL FORMAT 1-2-96)