JUL 29 1998

510(K) SUMMARY
MR ENDOSCOPIC VIDEO SYSTEM

Submitter Name: Greatbatch Scientific
a division of Wilson Greatbatch Ltd.

Submitter Address: 9645 Wehrle Drive
Clarence, New York 14031-1899

Contact Person: Gary J. Sfeir, RAC

Phone Number: 716.759.5655

Facsimile Number: 716.759.5654

Date Prepared: 22 May 1998

Device Trade Name: MR Endoscopic Video System

Device Common Name: Color Television Camera System

Classification Name: Camera, Television, Endoscopic

Predicate Devices:

Camera:	Endocam Corin, U.S.A. Tampa, FL
Video Monitor:	Sony PVM-1343MD Color Video Monitor Sony Medical Systems Montvale, NJ

Device Description: The MR Endoscopic Video System consists of a color camera signal processor (PAL or NTSC), camera head, color video monitor and all associated cables. The camera is powered by a 19 volt (PAL) or 15 volt (NTSC) battery pack. The video monitor is powered by a 110 volt AC to 12.5 volt DC medical-grade power supply attached to the end of a 20 foot shielded cable. The camera head attached to endoscopes by a non-conductive snap-lock coupling. The camera is connected to the video monitor via a cable. The endoscopic image can then be displayed to a remotely located video monitor.

Intended Use: To digitally generate and display an image captured from a rigid or flexible endoscope during a minimally invasive interventional MR surgical procedure.

Device Technological Characteristics and Comparison to Predicate Devices(s):	The device technological characteristics are similar in design to the predicate devices.
Performance Data:	The devices were tested for Electrical Safety and Electromagnetic Compatibility. They were also tested for MR Safety and were found to be acceptable in an interventional MR environment.
Conclusion:	The MR Endoscopic Video System as designed can be safely used in a MR environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1998

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

Re: K981856
Magna-Cam Camera and Magna-Pix Video Monitor
Dated: May 26, 1998
Received: May 27, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FET

Dear Mr. Sfeir:

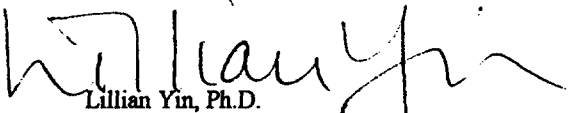
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 3

INDICATIONS FOR USE

510 (k) Number (if known): K 981856

Device Name: MR Endoscopic Video System

Indications For Use:

The MR Endoscopic Video System is intended to digitally generate and display an image captured from a rigid or flexible endoscope during a minimally invasive interventional MR surgical procedure.

(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 _____

(OPTIONAL FORMAT 1-2-96)

Robert R Catlin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 981856