K970619

510(k) SUMMARY
MR FIBER OPTIC INTUBATING LARYNGOSCOPE HANDLE

NOV 19 1997

Submitter Name:	Greatbatch Scientific a division of Wilson Greatbatch Ltd.
Submitter Address:	4100 Barton Road Clarence, New York 14031
Contact Person:	Gary J. Sfeir, RAC
Phone Number: **Facsimile Number:**	716.759.5277 716.759.5280
Date Prepared:	6 October, 1997
Device Trade Name:	MR Fiber Optic Intubating Laryngoscope Handle
Device Common Name: **Classification Name:**	Laryngoscope Rigid Laryngoscope
Predicate Devices:	Fiber Optic Laryngoscope Welch Allyn, Inc. Sun Lite™ Laryngoscope Sun Med, Inc. Heine Fiber Optic Laryngoscope Heine USA Ltd.
Device Description:	The MR Fiber Optic Intubating Laryngoscope consists of a handle which is manufactured from brass and is chrome plated. The cell used to provide the light source energy is a proprietary "c" size cell.
Intended Use:	The MR Fiber Optic Intubating Laryngoscope Handle when used with the laryngoscope blades stated in the package insert will be used to facilitate and aid in tracheal intubation in a MRI or an interventional MR environment, not to exceed a 1.5 Tesla static magnet field.
Device Technological	The technological characteristics of all of the devices are similar in design. The Greatbatch Scientific MR Fiber Optic Intubating Laryngoscope was tested in the center of a 1.5 Tesla static magnetic field, to assess artifact, RF Heating and the presence of attraction to the magnet. The device displayed an artifact level of twice the size of the device, less than 1° C of RF Heating, and a 4° angle of attraction. The device exhibited a 0° angle of attraction at the portal and at 15cm outside the magnet, which is the area of intended use.
Predicate Devices(s): **Performance Data:**	This device has been tested according to ASTM Standards F 965 and F 1185 and MR safety testing.

K970619

Conclusion:

The Greatbatch Scientific MR Fiber Optic Intubating Laryngoscope Handle is substantially equivalent in design and intended use to the predicate devices listed above. The only difference is that the Greatbatch Scientific MR Fiber Optic Laryngoscope can be safely used in a MRI or an interventional MR environment, not to exceed a 1.5 Tesla static magnetic field.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1997

Mr. Gary J. Sfeir
Greatbatch Scientific, Inc.
4100 Barton Road
Clarence, New York 14031

Re: K970619
MR Fiber Optic Laryngoscope Handle
Regulatory Class: I (one)
Product Code: 73 CCW
Dated: October 6, 1997
Received: October 8, 1997

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) 594-4648. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510 (k) Number (if known): K970619

Device Name: Greatbatch Scientific MR Fiber Optic Laryngoscope Handle

Indications For Use:

The Greatbatch Scientific MR Fiber Optic Laryngoscope Handle when used with a green color marking blade system, is intended to facilitate and aid in tracheal intubation in a Magnetic Resonance Imaging (MRI) or an interventional Magnetic Resonance (MR) environment, not to exceed a 1.5 Tesla static magnet field.

(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 ____

Christy Foreman (OPTIONAL FORMAT 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K970619