
510(k) SUMMARY
GREATBATCH SCIENTIFIC MR COMPATIBLE SINUSCOPE

OCT 31 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

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Date Prepared: 17 October, 1997

Device Trade Name: Greatbatch Scientific MR Compatible Sinuscope

Device Common Name: Sinuscope

Classification Name: Nasopharyngoscope

Predicate Devices: Optus Sinuscope and Accessories

Device Description: The Greatbatch Scientific MR Compatible Sinuscope is available in standard and autoclavable 2.7mm and 4.0mm sizes, with 0°, 30° or 70° angles.

Intended Use: For use by practitioners to examine and treat a patient's nasal cavity and nasal pharynx in a MR or an interventional MR environment, not to exceed a 1.5 Tesla static magnetic field.

Device Technological Characteristics and Comparison to Predicate Devices(s): The device technological characteristics are similar in design to the predicate device.

Performance Data: The device was tested for MR Compatibility and was found to be acceptable for use in a 1.5 Tesla static magnetic field. See attached MR Safety Testing Summary.

Conclusion: The Greatbatch Scientific MR Compatible Sinuscope and Accessories as designed can be used in a MR or an interventional MR environment not to exceed a 1.5 Tesla static magnetic field.

MR COMPATIBLE SINUSCOPE MR SAFETY TESTING SUMMARY

1. Magnetic Attraction and Torque

Static field strength- 1.5 Tesla / GE Signa 64 MHz MR System
Type of test- String deflection
Observed deflection - None
Observed torque - None

2. Artifact

Static field strength - 1.5 Tesla / GE Signa 64 MHz MR System
Sequences - 3
Amount of distortion:

| <u>Sequence</u> | <u>axial plane</u> | <u>sagittal plane</u> |
|-------------------|--------------------|-----------------------|
| FSPGR | +++ | +++ |
| T1 spin echo | ++ | ++ |
| T1 fast spin echo | ++ | ++ |

++ artifact same as the device

+++ artifact slightly larger than size of the device

3. RF Heating

A. Phantom:

Type of phantom - A rectangular-shaped plastic Plexiglas phantom filled with 45 liters of physiologic saline
Type of RF Coil - Body coil
SAR applied - 1.1 W/kg
Length of time - 26 minutes
Maximum temperature rise observed - <1.1°C

B. Clinical:

Type of RF coil - Head
SAR applied - 0.971 W/kg
Length of time - 15 minutes, 22 seconds
Maximum temperature rise observed 7°C

4. Gradient Induced Voltage

A. Phantom - No phantom tests were conducted.

B. Clinical - No adverse effects were observed in clinical tests conducted at a maximum gradient strength of 10 mT/m and risetime of 600 mSec.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

Gary J. Sfeir
Director, Regulatory Affairs
Greatbatch Scientific
4100 Barton Road
Clarence, New York 14031

Re: K971375
Greatbatch Scientific MR Compatible Sinuscope
Dated: September 26, 1997
Received: September 29, 1997
Regulatory class: II
21 CFR 874.4760/Procode: 77 EOB

Dear Mr. Steir:

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 requirement, 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/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): _____

Device Name: Greatbatch Scientific MR Compatible Sinuscope

Indications For Use:

The Greatbatch Scientific MR Compatible Sinuscope is intended for use in sinus endoscopy surgery in a MR or an interventional MR environment, not to exceed a shielded 1.5 Tesla magnet.

(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)

Edward C. Kigeron
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971375