

K971781

510(k) SUMMARY
GREATBATCH SCIENTIFIC MR COMPATIBLE
ARTHROSCOPES AND SMALL JOINT ARTHROSCOPES

NOV 21 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: 716.759.5277

Facsimile Number: 716.759.5280

Date Prepared: 30 October, 1997

Device Trade Name: Greatbatch Scientific MR Compatible Arthroscopes and Small Joint Arthroscopes

Device Common Name: Arthroscope

Classification Name: Arthroscope

Predicate Devices: Optus Arthroscopes and Mini Arthroscopes

Device Description: The Greatbatch Scientific MR Compatible Arthroscopes and Small Joint Arthroscopes are available in standard and autoclavable 1.7mm, 2.7mm and 4.0mm sizes, with 0°, 30° or 70° angles.

Intended Use: For use by practitioners to treat the small joints of the wrist, knee, ankles, elbow, shoulder, and the temporal-mandibular joint in patients 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 Device(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 magnet field. See attached MR Safety Testing summary.

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 1997

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

Re: K971781
Trade Name: Greatbatch Scientific MR Compatible Arthroscopes and Small Joint Arthroscopes
Regulatory Class: II
Product Code: HRX
Dated: September 5, 1997
Received: September 8, 1997

Dear Mr. Sfeir:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

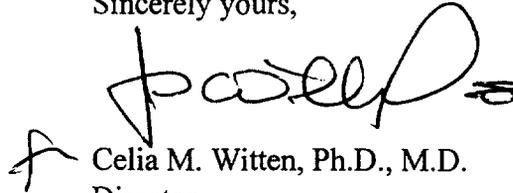
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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.

Page 2 - Mr. Gary J. Sfeir, RAC

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510 (k) Number (if known):

12971781

Device Name:

Greatbatch Scientific MR Compatible
Arthroscopes and Small Joint
Arthroscopes and Accessories

Indications For Use:

The Greatbatch Scientific MR Compatible Arthroscopes and Small Joint Arthroscopes and Accessories are intended for use by practioners to treat the small joints of the wrist, knee, ankles, elbow, shoulder, and the temporal- mandibular joint of patients 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

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

12971781