K122053 (1/2)

OCT 24 2012

510(k) Summary

Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Tammy Wharton Senior Regulatory Affairs Specialist OtisMed, Stryker Orthopaedics 1600 Harbor Bay Parkway, Suite 200 Alameda, CA 94502 Phone: (510) 995-4462
Date Prepared:	September 27, 2012
Proprietary Name:	ShapeMatch® Cutting Guides
Common Name:	Cutting Guide
Classification Name:	21 CFR §888.3560 Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Stryker® Patient Specific Cutting Guides, K110533

Device Description: The ShapeMatch Cutting Guides are single-use, disposable, cutting guides designed and manufactured from patient imaging data (MRI/CT). The cutting guides are used to aid the surgeon intra-operatively in making the initial distal femoral and the initial proximal tibial bone cuts during a total knee arthroplasty surgery. The cutting guides also establish the references for component orientations. The cutting guides are manufactured from polyoxymethylene per ASTM F1855.

The ShapeMatch Cutting Guides are intended for use with the Triathlon® Knee System (Cruciate Retaining (CR), Posterior Stabilized (PS) and Condylar Stabilizing (CS)) determined substantially equivalent via the following 510(k)s K031729, K040267, K042993, K051146, K051380, K053514, K062037, K061251, K063423, and K072575.

The accessory Triathlon® Extra-medullary (EM) Universal Goniometer is available for the surgeon to use intra-operatively to check the position of the femoral and tibial components. The goniometer mates with the saw slots on both the femoral and tibial guides for use in referencing the cuts with anatomic landmarks prior to resection of the bone. The accessory Triathlon® EM Universal Goniometer is made from Stainless Steel per ASTM A564.

Intended Use: The ShapeMatch Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee arthroplasty components

intraoperatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

Indications: The ShapeMatch Cutting Guides are intended for use with the CR, PS and CS components of the Triathlon® Knee System. The indications for use of the Triathlon Knee System when used with the ShapeMatch Cutting Guides are:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed reconstruction procedures which did not involve the implantation of hardware on the condylar surfaces

Additional Indications for Posterior Stabilized (PS):

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

The ShapeMatch Cutting Guides are intended for single use only.

Summary of Technologies: Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the predicate device.

Non-Clinical Testing:

Detailed software verification and validation were performed per FDA Guidance, "General Principles of Software Validation: Final Guidance for Industry and FDA Staff.

Clinical Testing: Not Applicable to validate changes.

Conclusion: The ShapeMatch Cutting Guides are substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

OCT 24 2012

Howmedia Osteonics Corp.
c/o Ms. Tammy Wharton
Senior Regulatory Affairs Specialist
OtisMed, Stryker Orthopaedics
1600 Harbor Bay Parkway, Suite 200
Alameda, CA 94502

Re: K122053
Trade/Device Name: ShapeMatch® Cutting Guides
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OOG
Dated: September 27, 2012
Received: October 3, 2012

Dear Ms. Wharton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter Rumm MD
Deputy Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122053

Device Name: ShapeMatch® Cutting Guides

Indications for Use:

The ShapeMatch Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee arthroplasty components intraoperatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The ShapeMatch Cutting Guides are intended for use with the CR, PS and CS components of the Triathlon® Knee System. The indications for use of the Triathlon Knee System when used with the ShapeMatch Cutting Guides are:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed reconstruction procedures which did not involve the implantation of hardware on the condylar surfaces

Additional Indications for Posterior Stabilized (PS):

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

The ShapeMatch Cutting Guides are intended for single use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices