K070236 1/2

510(k) Summary

Manufacturer:	rms Company 8600 Evergreen Boulevard Minneapolis, MN 55433 763-786-1520 – Office 763-783-5073
Submitted By:	Small Bone Innovations 1711 South Pennsylvania Avenue Morrisville, PA 19067
Proprietary Name:	SBI Lateral Radio Capitellum
Classification name:	Class II, 888. 3160 - Prosthesis, Elbow, Semi-Constrained, Cemented
Common/Usual Name:	Elbow joint metal/polymer semi-constrained cemented prosthesis
Substantial Equivalence:	Documentation is provided which demonstrated the SBI Lateral Radio Capitellum to be substantially equivalent to other legally marketed devices.
Device Description:	The SBI Lateral Radio Capitellar Implant provides an alternative to hemi-arthroplasty of the proximal radial head. The implant is used for the treatment of degenerative joint disorders of the radio-capitellar joint allowing activities of daily living to be performed with no or significantly reduced pain. The radio-capitellar implant is designed to be used with the radial stem components of the rHead and rHead Recon stem implants cleared for market under 510(k) K011819 and K023604 respectively.
Intended Use:	The SBI Radio-Capitellar implant is indicated for use in the elbow for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions: 1) non-inflammatory degenerative joint disease including osteo-arthritis or traumatic arthritis; 2) inflammatory degenerative joint disease including rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatments and devices have failed; and 5) treatment of fractures that are unmanageable using other techniques. The SBi Lateral

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Assembly Radio-Capitellar implant is intended for cemented use only.

Material:

ASTM F-648: Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants.
ASTM F-1537: Wrought Cobalt–28Chromium–6Molybdenum Alloys for Surgical Implants.
ASTM F1580: Titanium and Titanium–6Aluminum–4Vanadium Alloy Powders and Coatings of Surgical Implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2007

Small Bone Innovations
% Mr. Robert Hoehn
Regulatory Associate
Musculoskeletal Clinical Regulatory Advisers
505 Park Avenue, 14th Floor
New York, NY 10022

Re: K070236
Trade/Device Name: SBI Lateral Radio Capitellum
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDB
Dated: January 15, 2007
Received: January 25, 2007

Dear Mr. Hoehn:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchman for

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

Enclosure

Indications for Use

510(k) Number: K070236 1/1

Device Name: SBI Lateral rHead

Indications For Use:

The Small Bone Innovations' (SBi) Lateral Assembly Radio-Capitellar implant is indicated for use in the elbow for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions: 1) non-inflammatory degenerative joint disease including osteo-arthritis or traumatic arthritis; 2) inflammatory degenerative joint disease including rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatments and devices have failed; and 5) treatment of fractures that are unmanageable using other techniques.

The SBi Lateral Assembly Radio-Capitellar implant is intended for cemented use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bonehill

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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