K062898

NOV 13 2006

510(k) Summary

Manufacturer:	rms Company 8600 Evergreen Boulevard Minneapolis, MN 55433 763-786-1520 – Office 763-783-5073
Submitted By:	Small Bone Innovations James O' Connor 505 Park Avenue, 14th Floor New York, NY 10022 joconnor@totalsmallbone.com 215-428-1791 – Office 212-750-2112 - Fax
Proprietary Name:	SBI Lateral rHead Implant
Classification name:	Class II, 888.3170 - prosthesis, elbow, hemi-, radial, polymer
Common/Usual Name:	Elbow joint radial (hemi-elbow) polymer prosthesis
Substantial Equivalence:	Documentation is provided which demonstrated the SBI Lateral rHead Implant to be substantially equivalent to other legally marketed devices.
Device Description:	The SBi Lateral Assembly rHead prosthesis consists of a cobalt chromium stem and head. The stem of the implant is coated with CPTi coating and is designed to be inserted into the shaft of the proximal radius. The head of the implant articulates with the capitellum. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.
Intended Use:	The Radial Head Implant is intended for replacement of the proximal end of the radius: 1. Replacement of the radial head for degenerative, post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with: a. Joint destruction or subluxation visible on x-ray. b. Resistance to conservative treatment.

2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.

Material: ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants
ASTM F-1580 titanium powders for coating of surgical implants

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Small Bone Innovations
% Mr. James O'Connor
505 Park Avenue, 14th Floor
New York, New York 10022

NOV 13 2006

Re: K062898
Trade/Device Name: SBI Lateral rHead Implant
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: September 15, 2006
Received: September 27, 2006

Dear Mr. O'Connor:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buckup 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: K062898

Device Name: SBI Lateral rHead

Indications For Use:

The SBi Lateral Assembly rHead is intended for replacement of the proximal end of the radius:

1. Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:

    a. Joint destruction or subluxation visible on x-ray
    b. Resistance to conservative treatment

2. Primary replacement after fracture of the radial head

3. Symptomatic sequelae after radial head resection

Prescription Use √ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ann

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

510(k) Number K062898