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510(k) Summary

JUL 19 2006

Manufacturer:	Small Bone Innovations 1711 South Pennsylvania Ave Morrisville, PA 19067 215-428-1791
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 Ulnar Head Implant
Classification name:	Class II, 888.3810 - Prosthesis, Wrist, Hemi-, Ulnar
Common/Usual Name:	Ulnar Head Implant
Substantial Equivalence:	Documentation is provided which demonstrated the SBI Ulnar Head Implant to be substantially equivalent to other legally marketed devices.
Device Description:	The uHead™ Ulnar Head Replacement prosthesis is currently approved under 510(k) K010786 and marketed by Small Bone Innovations. This device is used to treat patients with rheumatoid, degenerative, or post-traumatic disabilities presenting the following; pain and weakness of the wrist joint not improved by conservative treatment, instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes, and failed ulnar head resection. The sigmoid notch component is used in conjunction with the uHead™ device. Dependent upon the severity of degenerative joint disease and forearm stability, the sigmoid notch component can be used to restore stabile wrist function and improve forearm kinematics that is not always obtainable with the uHead™ prosthesis alone.

Intended Use:	The SBI Ulnar Head Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following; pain and weakness of the wrist joint not improved by conservative treatment, instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes, and failed ulnar head resection.
Material:	The SBI Ulnar Head Implant is designed from implantable grades of cobalt chrome (ASTM 1537-94), with CpTi coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Small Bone Innovations
% Mr. James O'Connor
VP, QA/QC & Regulatory Affairs
505 Park Avenue, 14th Floor
New York, New York 10022

Re: K061146
Trade/Device Name: SBI Ulnar Head Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: Class II
Product Code: KXE
Dated: June 13, 2006
Received: June 19, 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.

Indications for Use

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Device Name: SBI Ulnar Head Implant

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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 Buchup

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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