JUN 19 2012

510(k) Summary K112030 (1/2)

Date Prepared: June 13, 2011

Sponsor: Synthes
Angela F. Lassandro
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6854

Device Name: Synthes Radial Head Prosthesis System

Classification: CLASS II, §888.3170 – Elbow joint radial (hemi-elbow) polymer prosthesis
Product Code: KWI

Predicate Device:
Biomet ExploR™ Radial Head Prosthesis System (K051385)
Ascension® Modular Radial Head (K032686)
Titan Endoskeleton Interbody Fusion Devices (K111626, K102067, K100889, K083714, and K080615)
Rhausler Plage Anterior Cervical Fusion System (K111272)
Straumann Dental Implant System (K053088 and K033984)
Synthes Epoca Titanium Humeral Stem (K072578)
Synthes Epoca Titanium Humeral Stem w/ (HA) Coating (K083439)

Device Description: The Synthes Radial Head Prosthesis is a two-piece modular system comprised of titanium alloy stem and cobalt chrome head components with an integral screw and side-loading application to allow for in situ assembly. The system consists of a range of lengths and diameters for the stem in both straight and curved configurations as well as heads in a range of diameters and heights to accommodate the surgical need.

Intended Use: The Synthes Radial Head Prosthesis System is indicated for the:

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

Revision following failed radial head arthroplasty

K112030 (2/2)

Substantial Equivalence:

The proposed Synthes Radial Head Prosthesis has the same indications for use, the same fundamental technological characteristics, and similar materials as the predicate Biomet ExploR™ (K051385) and Ascension® (K032686) Modular Radial Head Devices. In vitro performance testing demonstrates the ability of the proposed device to withstand the same clinical loads of the radiocapitellar joint.

Additionally, the Synthes Radial Head Prosthesis Stems have been shown to have similar surface characteristics to the Titan Endoskeleton Interbody Fusion Devices (K111626, K102067, K100889, K083714, and K080615), Rhausler Plage Anterior Cervical Fusion System (K111272), Straumann Dental Implant System (K053088 and K033984), Synthes Epoca Titanium Humeral Stem (K072578), Synthes Epoca Titanium Humeral Stem w/ (HA) Coating (K083439). Macro Surface Analysis (roughness, pore size, pore depth, etc.), Scanning Electron Microscopy (SEM), and X-Ray Photoelectron Spectroscopy (XPS) have been conducted to demonstrate similar macro- and micro- surface characteristics in comparison to existing devices. Additionally, a literature review has been conducted demonstrating relating the device surface characteristics to physiological responses.

Based on the discussed similarities in conjunction with performance testing, physical macro and micro surface analysis, surface chemistry analysis, and literature review the proposed Synthes Radial Head Prosthesis System does not raise any new issues of safety and effectiveness in comparison to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 19 2012

Synthes USA, LLC
% Ms. Angela F. Lassandro
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K112030
Trade/Device Name: Synthes Radial Head Prosthesis System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: May 17, 2012
Received: May 21, 2012

Dear Ms. Lassandro:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,

Erin M. Keith

for 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 Statement

510(k) Number (if known): K112030

Device Name: Synthes Radial Head Prosthesis System

Indications for Use:

The Synthes Radial Head Prosthesis System is intended for:

1. The replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with
   a. Joint destruction and/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

4. Revision following failed radial head arthroplasty.

Prescription Use X (Per 21 CFR 801.109) 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)

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

510(k) Number K112030