JAN 2 8 2003 K023851

Summary of Safety and Effectiveness
for
Precimed Hip Screw System

This safety and effectiveness summary for the Precimed Hip Screw System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
Precimed, Inc.
50 Devyn Drive
Chester Springs, PA 19425

Contact Person :
Barbara Lyons
50 Devyn Drive
Chester Springs, PA 19425
Telephone: (610) 524-8300

Date Prepared: November 15, 2002

2. Tradename: Precimed Hip Screw System
Common Name: Compression Hip Screw and Supracondylar Plate System
Classification Name: Single/ multiple component metallic bone fixation appliances and accessories (888.3030)

3. Predicate or legally marketed devices which are substantially equivalent:

- AMBI Hip Screw System (S &N Richards)
- HDS / DCS Dynamic Hip & Condylar Screw System (Synthes)
- Syntec-Taichung DHS / DCS Plate System (Syntec-Taichung Medical Instrument Co.)

4. Description of the device :

The Precimed Hip Screw System is a compression fixation system used for the treatment of femoral neck and distal femoral fractures. It consists of compression plates, lag screws, compression screws, bone screws and angled blade plates.

Materials: The devices are manufactured from 316 LVM stainless steel or Titanium alloy 6Al-4V per ASTM and ISO standards.

Function: The system functions to provide immediate stability and temporary fixation during the natural healing process following fractures of the femoral neck or distal femur.

5. Intended Use:

The Precimed Hip Screw System is indicated for use in the treatment of dis-placed sub-capital fractures, subtrochanteric and intertrochanteric fractures, arthrodesis, moderately displaced femoral capital epiphysis, varus or valgus osteotomies of the hip, medial displacement osteotomies, supracondylar and distal femoral fractures.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Precimed Hip Screw System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2003

Ms. Barbara Lyons
Precimed, Inc.
50 Devyn Drive
Chester Springs, Pennsylvania 19425

Re: K023851
Trade Name: Precimed Hip Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: November 15, 2002
Received: November 19, 2002

Dear Ms. Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (301) 594-4659. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K023851

Device Name : Precimed Compression Hip Screw System

Indications For Use : K023851

The Precimed Hip Screw System is indicated for use in the treatment of dis-placed sub-capital fractures, subtrochanteric and intertrochanteric fractures, arthrodesis, moderately displaced femoral capital epiphysis, varus or valgus osteotomies of the hip, medial displacement osteotomies, supracondylar and distal femur fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X
(PER 21 CFR 801.109)

OR

Over-the-counter use _____

(optional format 1-2-96)

for Division Sign-Off)
Division of G... Restorative
...d Neurolog... ...ices

K023851