JUL 3 0 2004

K041355
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510(K) SUMMARY
HUMERAL STAPLE

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6670
CONTACT PERSON:	John Reabe
DATE SUMMARY PREPARED:	March 8, 2004
TRADE OR PROPRIETARY DEVICE NAME:	Humeral Staple
COMMON OR USUAL NAME:	Intramedullary fixation fastener
CLASSIFICATION NAME:	Smooth or threaded metallic bone fixation fastener
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedic/87

DEVICE INFORMATION:

INTENDED USE:
Humeral staples are intended for fixation of two-part proximal humerus fractures and three-part proximal humerus fractures in conjunction with limited internal fixation such as suture wire. The device is intended for single use.

Humeral staples are manufactured from either Stainless Steel (ASTM F 138) or Titanium (ASTM F 1472). The staple features two trocar point ends and suture holes. The staple is designed for intramedullary implantation in the proximal humerus.

DEVICE DESCRIPTION:
Humeral staples are manufactured from either Stainless Steel (ASTM F 138) or Titanium (ASTM F 1472). The staple features two trocar point ends and suture holes. The staple is designed for intramedullary implantation in the proximal humerus.

SUBSTANTIAL EQUIVALENCE INFORMATION:
The humeral staple is similar to the DePuy ACE, Inc., The Nancy Nail (K032687); Synthes, Elastic Intramedullary Nail (K971783); Smith & Nephew, Inc., Ender Nail (K811002); and Smith & Nephew, Inc., Steinman Pin (preamendment device) in that all the devices are made of stainless steel or titanium, offered in similar diameters and lengths, and have similar indications related to long bone or extremity fractures.

The humeral staple is substantially equivalent to the other predicate devices. The difference between the humeral staple and predicate devices is the humeral staple is U-shaped and the other products are not U-shaped, but are used in multiples.

SUMMARY OF TECHNOLOGICAL COMPARISON:
The humeral staple is substantially equivalent to the predicate devices listed in the previous section in terms of material, indications for use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Mr. John Reabe
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K041355
Trade/Device Name: Humeral Staple
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HTY
Dated: May19, 2004
Received: May 20, 2004

Dear Mr. Reabe:

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.

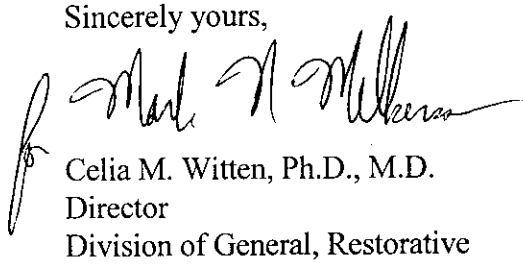
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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,



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): K041355

Device Name: Humeral Staple

Indications for Use:

Humeral staples are intended for fixation of two-part proximal humerus fractures and three-part proximal humerus fractures in conjunction with limited internal fixation such as suture wires. The device is intended for single use.

(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 Mark N Milhouse

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

510(k) Number K041355