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510 (k) Summary

a. Device Classification Name:
Plate, Fixation, Bone

b. Regulation Class / Number:
Class II, Section 888.3000

c. Device Name:
Normed Compression Bone Screw System

d. Product.Code:
HRS
e. Classification / Review Advisory Committee:
Orthopedic

The Normed Compression Bone Screw System is a headless screw with double self-tapping cancellous bone thread that is designed for dynamic adjustable intarfragmentary compression purposes. The pitch of the thread in the proximal segment is smaller than the thread pitch at the distal end. The compression force is produced due to the difference in pitch between the distal and proximal segments. The Normed Compression Bone Screw System consists of three systems, Mini System 1.5, Standard System 2.0 and High Compression System 2.0. The Mini System 1.5 may be placed using an open approach with the use of a target bow device for placement of the screw. The Standard System 2.0 and High Compression System 2.0 are cannulated and may be placed through percutaneous screw placement using K-wire as a guide in minimize the incision. All three systems are available in10 through 30 mm length.

The Normed Compression Bone Screw System intended for use for fractures or arthrodesis of carpals and metacarpals, radial head and radial stolid fractures, metatarsal fractures and osteotomies of the forefoot and intra- artcular arthrodesis in the wrist, pseudo-arthrosis, degenerative alteration and corrective osteotomies aiming to functionally stable osteosynthesis such as, but not limited to scaphoid fractures, fractures of other carpal bones, scaphoid pseudo-arthrosis, intercarpal arthrodesis, arthrodesis of finger eng and metacarpal joints and fractures of ulna head and radius head.

Official Contact Person:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

Mr. Albert Enayati
President
Noviace Corporation
809 Carter Lane
Paramus, NJ 07652

Re: K032634
Trade/Device Name: Normed Compression Bone Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDS
Dated: August 22, 2003
Received: September 12, 2003

Dear Mr. Enayati:

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,

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

Indications for use

510 (k) Number (if known): K032634

Device Name: Normed Compression Bone Screw System

Indications for use:

The Normed Compression Bone Screw System intended for use for fractures or arthrodesis of carpals and metacarpals, radial head and radial stolid fractures, metatarsal fractures and osteotomies of the forefoot and intra- artcular arthrodesis in the wrist, pseudo-arthrosis, degenerative alteration and corrective osteotomies aiming to functionally stable osteosynthesis such as, but not limited to scaphoid fractures, fractures of other carpal bones, scaphoid pseudo-arthrosis, intercarpal arthrodesis, arthrodesis of finger eng and metacarpal joints and fractures of ulna head and radius head.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use_____ OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

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

510(K) Number K032634