K113106

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510(k) Summary for the DNE External Fixation System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the DNE External Fixation System

JAN - 4 2012

1. GENERAL INFORMATION

Date Prepared: October 7, 2011

Trade Name: DNE External Fixation System

Common Name: External fixation frame

Classification Name: Single/multiple component metallic bone fixation appliances and accessories.

Class: Class II per 21 CFR section 888.3030

Product Code: KTT

CFR section: 21 CFR section 888.

Device panel: Orthopedic

Legally Marketed Predicate Device: R&R External Fixator System (K052005)

Submitter: DNE, LLC
2225 Park Place Drive
Slatington, Pa. 18080
TEL. (610)-442-101

Contact: J.D. Webb
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Round Rock, TX 78681
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2. DEVICE DESCRIPTION

The DNE External Fixation System assembly consists of three basic types of elements: 1) bone anchorage elements, 2) bridge elements, and 3) connection elements. The design allows freedom of pin placement, ease of assembly and stable fixation of bone fragments with the possibility of axial loading of the extremity and immediate range of motion of all adjacent joints.

Bone anchorage elements include pins and wires. Bridge elements include rings or arches and extensions. Connection elements include struts, nuts and bolts, wire fixation bolts and pin clamps.

Materials:
Aluminum, Ti6Al4V alloy, stainless steel

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The DNE External Fixation System is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The DNE External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The DNE External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

5. NON-CLINICAL TEST SUMMARY

No testing was performed.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

The DNE External Fixation System is substantially equivalent to the predicate device in terms of indications for use, design, material, performance and function.

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

DNE, LLC
% Mr. J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681

JAN - 4 2012

Re: K113106
Trade/Device Name: DNE External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances & Accessories
Regulatory Class: II
Product Code: KTT
Dated: October 17, 2011
Received: October 20, 2011

Dear Mr. Webb:

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 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

510(k) Number (if known): K113106

Device Name: DNE External Fixation System

Indications for Use:

The DNE External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The DNE External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

Prescription Use X
(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

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

510(k) Number K113106