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.

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
   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
   1001 Oakwood Blvd
   Round Rock, TX 78681
   TEL. (512)-388-0199
   e-mail: jdwebb@orthomedix.net

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

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” (21 CFR 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

Sincerely yours,

[Signature]

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)

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

510(k) Number K113106