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OCT 27 2005

DVO Extremity Solutions 720 E. Winona Ave., Warsaw, IN 46580 877-777-9DVO

510(k) Summary of Safety and Effectiveness

SUMMARY PREPARED:	September 28, 2005
510(k) SPONSOR/APPLICANT:	DVO Extremity Solutions, LLC 720 E. Winona Ave., Warsaw, IN 46580
510(k) PREPARER and CONTACT PERSON:	Dina L. Weissman, J.D. P.O. Box 205, Derby CT 06418 Telephone: (203) 287-0485, Email: DLWeissman@aol.com
TRADE NAME:	Wrist Fusion Plate
COMMON NAME:	Plate, Fixation, Bone
CLASSIFICATION:	Class II per 21 CFR § 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
DEVICE PRODUCT CODE:	87 LXT
PREDICATE DEVICES:	Synthes, Wrist Fusion Plates, K000558, cleared 14 April 2000
DEVICE DESCRIPTION:	These anatomically contoured plates are offered in two lengths (standard or short), manufactured from either titanium (ASTM F-136) or stainless steel (ASTM F-138 or ASTM F-2229). The plate contains a single row of screw holes (2.4mm, 2.7mm and 3.2mm in diameter) down its length. The locking screws are 2.4mm in diameter and vary in length from 6mm to 14mm. The 2.7mm and 3.2mm screws were previously cleared. In addition to the screws, the device utilizes a press fit intramedullary fixation for the proximal stem.
INTENDED USE:	For wrist arthrodesis and for fractures of other small long bones such as the clavicle and olecranon. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities. Single use device for cementless use only.
COMPARISON TO PREDICATES:	The Wrist Fusion Plate is similar to the listed predicate device in intended use, performance characteristics, materials of construction, manufacturing methods and design. Biomechanical comparisons confirm similar mechanical properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DVO Extremity Solutions, LLC
c/o Dina L. Weissman, J.D.
P.O. Box 205
Derby, Connecticut 06418

OCT 27 2005

Re: K052754
Trade/Device Name: Wrist Fusion Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: September 28, 2005
Received: September 30, 2005

Dear Ms. Weissman:

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 (240) 276-0120. 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/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K052754

Device Name: Wrist Fusion Plate

Indications for Use:

For wrist arthrodesis and for fractures of other small long bones such as the clavicle and olecranon. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

This single use device is for cementless use only.

Prescription Use XXXXX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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 General, Restorative, and Neurological Devices

510(k) Number K052754