K052150 1/1

SEP - 8 2005

DVO
Extremity Solutions

## 510(k) Summary of Safety and Effectiveness

**SUMMARY PREPARED:** 5 AUGUST 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
Tel: (203) 287-0485, Email: DLWeissman@aol.com

**TRADE NAME:** Volar Plate System

**COMMON NAMES:** Plate, Fixation, Bone and Screw, Fixation, Bone

**CLASSIFICATION:** Class II per 21 CFR § 888.3030 (single/multiple component metallic bone fixation appliances and accessories) and 21 CFR § 888.3040 (smooth or threaded metallic bone fixation fastener)

**DEVICE PRODUCT CODE:** 87 HRS and 87 HWC

**PREDICATE DEVICES:**
Hand Innovations, Distal Volar Radius Fracture Repair System, K002775, cleared 5 Dec 2000
Synthes, Distal Radius Plate System, K982732, cleared 8 Oct 1998

**DEVICE DESCRIPTION:**
This non-sterile volar plate system offers several sizes and styles of volar plates, in either titanium (ASTM F-136) or stainless steel (ASTM F-138 or ASTM 2229). The three versions include a volar T-plate, a volar imtramedullary T-plate and a volar T-plate with translating head.

The distal head of the plate contains two rows of fixed angle screw holes that accept 2.7 mm screws. Dorsal and ulnar sheaths are secured into the plate recesses to cover the screw heads.

The screws vary in length from 16mm to 26mm. K-wires may also be used for stabilization of bone fragments.

**INTENDED USE:**
The DVO™ Volar Plate System is intended for volar fixation of fractures and osteotomies involving the distal radius. This single use device is for cementless use only.

**COMPARISON TO PREDICATES:**
The Volar Plate System is similar to the listed predicate devices in intended use, performance characteristics, materials of construction, manufacturing methods and design. This is evidenced by comparison of technological characteristics, dimensional analysis and finite element analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

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

Re: K052150
Trade/Device Name: Volar Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 5, 2005
Received: August 8, 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/dsma/dsmamain.html

Sincerely yours,

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): _____

**Device Name:** Volar Plate

**Indications for Use:**

The DVO™ Volar Plate System is intended for volar fixation of fractures and osteotomies involving the distal radius.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052150