

**510(k) Summary  
for the DC Ulnar Shortening System**

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In accordance with 21 CFR 807.92 of the Federal Code of Regulations  
the following 510(k) summary is submitted for the DC Ulnar Shortening System.

Date Prepared: February 20, 2008

FEB 29 2008

- 1. Submitter:**  
OrthoPro LLC  
3450 Highland Dr., #303  
Salt Lake City, UT 84106

**Contact Person:**  
J.D. Webb  
The OrthoMedix Group, Inc.  
1001 Oakwood Blvd  
Round Rock, TX 78681  
Telephone: 512-388-0199
- 2. Trade name:** DC Ulnar Shortening System  
**Common Name:** Bone plate  
**Classification Name:** Single/multiple component metallic bone fixation appliances and accessories  
Class II per 21 CFR section 888.3030  
HRS
- 3. Predicate or legally marketed devices which are substantially equivalent:**  
The DC Ulnar Shortening System is substantially equivalent to similar previously cleared ulnar osteotomy bone plates and screws.
- 4. Description of the device:**  
The DC Ulnar Shortening System is an implant intended for fixation of the ulna to assist healing. The implant is fabricated from titanium alloy. It is fixated with 3.5mm fixation screws and a 3.5mm self drilling self tapping headless interfragmentary screw. In addition to the plate and screws, there are instruments intended to assist with the procedure.

**Materials:**  
All implants in this system are made from titanium alloy Ti6Al4V for implantable devices in accordance with standard ASTM F 136.

**Function:**  
Provide fixation for osteotomies of the ulna.
- 5. Intended Use:**  
The DC Ulnar Shortening System provides fixation for osteotomies of the ulna.
- 6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:**  
The DC Ulnar Shortening System is similar to the predicate devices in terms of indications for use, design, material, and function.



FEB 29 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Orthopro, LLC  
% Mr. J. D. Webb  
The Orthomedix Group, Inc  
1001 Oakwood Blvd.  
Round Rock, TX 78681

Re: K073228  
Trade/Device Name: DC Ulnar Shortening System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation  
appliances and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: February 20, 2008  
Received: February 25, 2008

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.

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.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
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): K073228

Device Name: DC Ulnar Shortening System

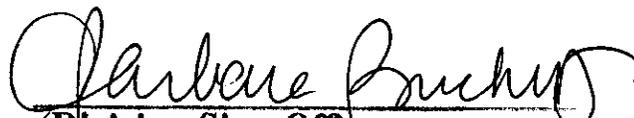
Indications for Use:

The DC Ulnar Shortening System provides fixation for osteotomies of the ulna.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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 General, Restorative,  
and Neurological Devices**

**510(k) Number** K073228