

**510(k) Summary
for the Disco Subtalar Implant**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted
for the Disco Subtalar Implant

1. GENERAL INFORMATION

Date Prepared: June 17, 2011

Trade Name: Disco Subtalar Implant

Common Name: Subtalar spacer

Classification Name: Screw, fixation, bone

Class: II

Product Code: HWC

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed: Trilliant Twist Subtalar Implant – Trilliant Surgical, LTD, K103183

Predicate Device: ProStop – Arthrex, K071456

Submitter: Trilliant Surgical LTD
602 Sawyer Street, Suite 120
Houston, TX 77007
Telephone: 214-288-1035

Contact: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199
e-mail: ortho.medix@sbcglobal.net

2. DEVICE DESCRIPTION

The Disco Subtalar Implant consists of a threaded implant, designed to be inserted between the posterior and middle facets of the subtalar joint, and corresponding instrumentation to facilitate insertion. The leading end of the implant is cylindrical in shape and is approximately half of the overall length of the device, with the remaining length being spherical. The full length of the implant incorporates a center cannula designed for use with a guide wire to facilitate proper placement of the implant. Internal threads are machined in the spherical end of the implant and are for use with a removal tool.

Change from Predicate:

The change from the predicate device is a geometry change.

Materials:

Ti-6Al-4V alloy per ASTM F136

Function:

The Disco Subtalar Implant blocks the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation.

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3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Disco Subtalar Implant is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The Disco Subtalar Implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is intended to block the forward, downward, and medial displacement of the talus, thus allowing normal subtalar joint motion but limiting excessive pronation.

5. NON-CLINICAL TEST SUMMARY

Static compression performed.

The results of this testing indicate that the Disco Subtalar system is equivalent to predicate devices.

Static compression and pull-out testing was performed

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

The Disco Subtalar Implant is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Trilliant Surgical LTD
% The OrthoMedix Group, Inc.
% Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

DEC - 6 2011

Re: K111834

Trade/Device Name: Disco Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: October 25, 2011
Received: November 1, 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M" and "N".

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): K111834

Device Name: Disco Subtalar Implant

Indications for Use:

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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)

Michael A. Lewis for MxM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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