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510(k) Summary
for the Trilliiant Surgical Subtalar Implant

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

Date Prepared: October 22, 2010

FEB - 8 2011

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

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Trilliant Surgical Subtalar Implant
Common Name: Subtalar spacer
Classification Name: Screw, fixation, bone
21 CFR section 888.3040
HWC
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
The Trilliant Surgical Subtalar Implant is substantially equivalent to the following devices:
   - Subtalar MBA System, K960692 (Kinetikos Medical, Inc.)
   - HyProCure Subtalar Implant System, K042030 (GraMedica Medical Technologies, LLC)
   - Subtalar Arthroereisis Implant, K093820 (Memometal Technologies)

4. **Description of the device:**
The Trilliant Surgical 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 implant is cylindrical in shape and incorporates a center cannula designed for use with a guide wire to facilitate proper placement of the implant.. It is available in six sizes, Ø7mm to Ø12mm in 1mm increments.

Materials:
Ti-6Al-4V alloy per ASTM F136

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

5. **Substantial equivalence claimed to predicate devices**
The Trilliant Surgical Subtalar Implant is substantially equivalent to the Subtalar MBA System, HyProCure Subtalar Implant System and Subtalar Arthroereisis Implant devices in terms of intended use, design, and materials used. The table below compares the features and characteristics of the Trilliant Surgical Subtalar Implant to these predicate devices.

Device Name / Items	Trilliiant Surgical Subtalar Implant	Subtalar MBA System	HyProCure Subtalar Implant System	Subtalar Arthroereisis Implant
Sponsor	Trilliant, LTD	Kinetikos Medical, Inc.	GraMedica Medical Technologies, LLC	Memometal Technologie
510(k) Number	N/A	K960692	K042030	K093820

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Items \ Device Name	Trilliiant Surgical Subtalar Implant	Subtalar MBA System	HyProCure Subtalar Implant System	Subtalar Arthroereisis Implant
Device Classification Name	Screw, fixation, bone	Screw, fixation, bone	Screw, fixation, bone	Screw, fixation, bone
Product Code	HWC	HWC	HWC	HWC
Regulation #	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040
Classification	II	II	II	II
Indications for Use	[1] see at end of table	[2] see at end of table	[3] see at end of table	[4] see at end of table
Implant material	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136
Diameter **Length**	Ø - 7mm-12mm L - 12.75mm-19.50mm	Ø – 6mm-12mm L – 15mm		Ø – 6.5mm-11.5mm
Profile /anatomy location	Threaded cylinder / sinus tarsi	Threaded cylinder /sinus tarsi	Threaded cylinder /sinus tarsi Smooth cone / sinus canalis	Threaded cylinder /sinus tarsi Shallow thread to smooth cone / sinus canalis
Cannulated	Yes	Yes	Yes	Yes
Rounded nose for ease of insertion	Yes	Yes	Yes	No
Packaged sterile	No, sterilized at hospital	No, sterilized at hospital	Yes	Yes

[1] The Trilliant Surgical subtalar implant is indicated for the 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.

[2] The KMI Subtalar MBA System™ is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is design to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela:

- Severely pronated foot.
- Walking intemperance.
- Calcaneal stance position greater than 5°
- Manually correctable deformity
- Mid-tarsal breech (arch pain)
- Forefoot varus greater than 10°

[3] The HyProCure Subtalar Implant is indicated for use in the treatment of the hyperpronated foot by stabilization of the subtalar joint. The implant is designed to block anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

[3] The Memometal Technologies' Subfix Arthroereisis Implant is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing subtalar joint motion but blocking excessive pronation and the resulting sequela.

6. **Intended Use:**

The Trilliant Surgical subtalar implant is indicated for the 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.

7. **Non-clinical Test Summary:**

The following tests were conducted:

- Compression testing comparing predicate and Trilliant Surgical Subtalar Implant.

8. **Clinical Test Summary**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

The Trilliant Surgical Subtalar Implant is substantially equivalent to the predicate devices in terms of indications for use, design, material, 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 Blvd.
Round Rock, Texas 78681

FEB - 8 2011

Re: K103183
Trade/Device Name: Trilliant Surgical Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: January 28, 2011
Received: February 3, 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,

for

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): K103183

Device Name: **Trilliant Surgical Subtalar Implant**

Indications for Use:

The Trilliant Surgical Subtalar Implant is indicated for the 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.

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)

for M. Melkerson

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

510(k) Number K103183