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NOV 7 2012

510(k) Summary
for the Trilliant Hammer Toe Implant

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

1. GENERAL INFORMATION

Date Prepared: September 18, 2012

Trade Name: Hammer Toe Implant

Classification Name: Screw, Fixation, Bone

Class: II

Product Code: HWC

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Device: DigiFuse™ - K111536
Tiger Cannulated Screws – K081510

Submitter: Trilliant Surgical LTD
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Houston, TX 770081

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2. DEVICE DESCRIPTION

The Hammer Toe Implant is a threaded/spaded device used for bone fixation in the phalanges of the lesser digits in the foot and hand. The implant, which is a cannulated, threaded and spaded device, is offered in multiple diameters and lengths. The system will also consist of K-wires (K121008) to be used in the delivery of the implant and also for use of temporary stabilization of outlying joints.

Change from Predicate:

Both the Hammer Toe Implant and the predicate Tiger Cannulated Screws have a self tapping threaded section and both are cannulated for use with K-wires. The thread dimensions are the same for both devices. Opposite the threads the Tiger screws have a smooth section ending in a head. The Hammer Toe components have a tri-spade configuration at the proximal end.

Materials:

Titanium alloy per ASTM F136

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

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

4. INTENDED USE

The Hammer Toe System implants are intended for fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the lesser toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

5. NON-CLINICAL TEST SUMMARY

Testing per ASTM F543 included:

- Static axial pull-out of threaded portion from polyurethane foam test block,
- Static axial pull-out of barbed (spade) section from polyurethane foam test block,
- Driving torque into polyurethane foam test block and
- Static testing to determine failure torque

The results of this testing indicate that the Hammer Toe System is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Trilliant Surgical considers the Hammer Toe System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Trilliant Surgical LTD
% J.D. Webb
1001 Oakwood Blvd.
Round Rock, Texas 78681

Letter Dated: November 7, 2012

Re: K122959
Trade/Device Name: Hammer Toe Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September18, 2012
Received: September 25, 2012

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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122959

Device Name: Hammer Toe System

Indications for Use:

The Hammer Toe System implants are intended for fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the lesser toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

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)

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

510(k) Number K122959