**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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

OCT 2 0 2011

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

Re: K112737
Trade/Device Name: Tiger Headless Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth & threaded metallic bone fixation fasteners
Regulatory Class: II
Product Code: HWC
Dated: September 14th, 2011
Received: September 20th, 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): K112737

Device Name: Tiger Headless Cannulated Screws

Indications for Use:

The Tiger Headless Cannulated Screws are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones In the hand and foot.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for MJM

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

510(k) Number K112737

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 14, 2016

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

Re: K153338
Trade/Device Name: Tiger Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 13, 2015
Received: November 19, 2015

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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.

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Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K153338

Device Name
Tiger Cannulated Screw System

Indications for Use *(Describe)*

The Tiger Cannulated Screw System is indicated for fixation of fractures, non-unions, arthrodeses, and osteotomies of bones appropriate for the size of the device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

## *5*10(k) Summary:

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

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| **Date Prepared** | November 13, 2015 |
| **Submitted By** | Trilliant Surgical, LTD<br>6721 Portwest Dr,<br>Suite 160<br>Houston, TX 77024<br>713-388-6055 Tele<br>jolson@trilliantsurgical.com |
| **Contact** | J.D. Webb<br>1001 Oakwood Blvd<br>Round Rock, TX 78681<br>512-388-0199 Tele<br>e-mail: jdwebb@orthomedix.net |
| **Trade Name** | Tiger Cannulated Screw System |
| **Common Name** | Bone screws |
| **Classification Name** | Smooth & threaded metallic bone fixation fasteners |
| **Class** | II |
| **Product Code** | HWC |
| **CFR Section** | 21 CFR section 888.3040 |
| **Device Panel** | Orthopedic |
| **Primary Predicate Device** | Tiger Cannulated Screw System - K081510 / K112737 |
| **Secondary Predicate Devices** | Synthes Cannulated Screws - K962011 / K963172 / K963192 / K021556<br>Osteomed ExtremiFix Cannulated Screw System **-** K063298 / K151021 |
| **Device Description** | The Tiger Cannulated Screw System is a headed and headless, cannulated, self-drilling, self-tapping screw system for the management of bone orthopedic osteotomies and trauma. The system consists of Ø2.0-Ø7.0 mm screws and washers, and the necessary instruments to facilitate the placement of these implants.<br>The purpose of this submission is to add Ø5.5 mm and Ø7.0 mm headed cannulated screws to the Tiger Cannulated Screw System and to modify the indications for use statement for previously cleared devices (K081510 / K112737). |
| **Materials** | Titanium alloy, Ti-6Al-4V (ASTM F136) |
| **Substantial Equivalence Claimed to Predicate Devices** | The Ø5.5 mm and Ø7.0 mm Tiger Cannulated Screws and Washers are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. |

## *5*10(k) Summary:

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

| | |
|---|---|
| **Indications for Use** | The Tiger Cannulated Screw System is indicated for fixation of fractures, non-unions, arthrodeses, and osteotomies of bones appropriate for the size of the device. |
| **Non-clinical Test Summary** | The following analyses were conducted:<br><br>ASTM F543-07<br>• Torque to Failure<br>• Axial Pullout Strength<br>• Axial Pull Through Strength<br>• Driving/Insertion and Removal Torque<br><br>The results of these evaluations indicate that the Tiger Cannulated Screws are equivalent to predicate devices. |
| **Clinical Test Summary** | No clinical studies were performed |
| **Conclusions: Non-clinical and Clinical** | Trilliant Surgical considers the Ø5.5 mm and Ø7.0 mm Tiger Cannulated Screws and Washers to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use |