



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

Neosteo  
% JD Webb  
Official Correspondent  
The Orthomedix Group, Inc  
1001 Oakwood Blvd  
Round Rock, Texas 78681

November 25, 2015

Re: K153182

Trade/Device Name: Self- Compressive Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: October 30, 2015  
Received: November 3, 2015

Dear JD 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 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" (21 CFR 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 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>.

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

## Indications for Use

510(k) Number (if known)

K153182

Device Name

Self Compressive Screw

Indications for Use (Describe)

The Self-Compressive Screws are intended for the fixation of bone fractures and for bone reconstruction in the hand and in forefoot surgery.

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)



**510(k) Summary**

*Version 1*

*Preparation Date:*

*May 2013*

**I. SUBMITTER'S INFORMATION**

**A. 510(k) Owner**

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**B. Contact Person**

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**C. Date of Preparation of the 510(k) Summary**

30<sup>th</sup> October 2015

**510(k) Summary**

Version 1

Preparation Date:

May 2013

**II. DEVICE IDENTIFICATION****A. Trade or proprietary name**

Self-Compressive Screw

**B. Common or usual name**

Self-compressive screw range

**C. Classification name**

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040, Product code HWC)

**D. Class**

II

**E. Product code**

HWC

**F. CFR section**

21 CFR 888.3040

**G. Device panel**

Orthopedic

**H. Primary predicate device**

The Self-Compressive Screw is similar to the following predicate device which has been cleared via the premarket notification process: Self-Compressive Screw (K131471).

**I. Secondary predicate device**

The Self-Compressive Screw is similar to the following predicate device which has been cleared via the premarket notification process: Newclip Foot and Hand Motion System (K091118).

**510(k) Summary***Preparation Date:**May 2013***III. DEVICE DESCRIPTION**

The Self-Compressive Screw consists of screws available in several diameters and lengths.

All the implants are made of titanium alloy.

The fixation is provided thanks to the threading of the screw, which allows compression.

**A. Materials**

Titanium alloy per ASTM F136

**IV. INTENDED USE**

The Self-Compressive Screws are intended for the fixation of bone fractures and for bone reconstruction in the hand and in the forefoot surgery.

**V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE**

The Self-Compressive Screw is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.

**VI. NON-CLINICAL TEST SUMMARY**

The following mechanical tests were performed:

- Resistance to torsion according to ASTM F543 – Annex 1
- Pull-out strength according to ASTM F543 – Annex 3.

The results of these testing indicate that the current Self-Compressive Screw is equivalent to predicate device.

**VII. CLINICAL TEST SUMMARY**

No clinical studies were performed.



**510(k) Summary**

**VIII. CONCLUSIONS NON-CLINICAL AND CLINICAL**

NEOSTEO considers the current Self-Compressive Screw to be equivalent to the predicate device listed above. This conclusion is based on the devices' similarities in principles of operation, technology, materials and indications for use.