



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Neosteo
% Mr. J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

May 8, 2015

Re: K150772

Trade/Device Name: Snap-off 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: March 13, 2015
Received: April 1, 2015

Dear Mr. J. D. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K150772

Device Name

Snap-Off Self-Compressive Screws

Indications for Use (Describe)

The Snap-Off Self-Compressive Screws are intended for the fixation of bone fractures and for bone reconstruction 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

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

19th March 2015



510(k) Summary

II. DEVICE IDENTIFICATION

	"Screw" type devices
<u>Trade or proprietary name</u>	Snap-Off Self-Compressive Screw
<u>Common or usual name</u>	Self-compressive screw
<u>Classification regulation</u>	21 CFR 888.3040
<u>Proposed Regulatory Class</u>	Class II
<u>Panel</u>	87 "Orthopedic"
<u>Product code</u>	HWC
<u>Primary Predicate Device</u>	Spin® Snap-Off Screw (K991477) from NewDeal SA
<u>Secondary Predicate Device</u>	Self-Compressive Screws (K131471) from Neosteo

III. DEVICE DESCRIPTION

The Snap-Off Self-Compressive Screw consists of screws available in several 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

Snap-Off Self-Compressive Screw: Titanium alloy per ASTM F136



510(k) Summary

IV. INTENDED USE

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

V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

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

VI. NON-CLINICAL TEST SUMMARY

Snap-Off Self-Compressive Screw:

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 Snap-Off Self-Compressive Screw is equivalent to predicate devices.

VII. CLINICAL TEST SUMMARY

No clinical studies were performed.

VIII. CONCLUSIONS NON-CLINICAL AND CLINICAL

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