K121277

NOV 7 2012

510(k) Summary

DATE OF APPLICATION: 2012-04-25

APPLICANT: Z-Medical GmbH & Co. KG
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CONTACT PERSON: Alexander Henninger
Quality Manager
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1. Device Name

1.1. Snap Off Screw

Trade Names: Z-Snap Off Screw
Common Name: Snap Off Screw
Classification Name: Screw, fixation, bone

1.2. Double Thread Compression Screw

Trade Names: Z-Double Thread Compression Screw
Common Name: Double Thread Compression Screw
Classification Name: Screw, fixation, bone

1.3. Guide Wire

Trade Names: Z-Guide Wire
Common Name: Guide Wire, Kirschner
Classification Name: Pin, fixation, smooth

1.4. Staple

Trade Names: Z-Staple
Common Name: Staple
Classification Name: Staple, fixation, bone

2. Classification Product Code / Subsequent Code

2.1. Z-Snap Off Screw

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Screw, fixation, bone	Part 888	Orthopedic	HWC	2	888.3040

2.2. Z-Double Thread Compression Screw

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Screw, fixation, bone	Part 888	Orthopedic	HWC	2	888.3040

2.3. Z-Guide Wire

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Pin, fixation, smooth	Part 888	Orthopedic	HTY	2	888.3040

2.4. Z-Staple

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Screw, fixation, bone	Part 888	Orthopedic	JDR	2	888.3030

3. Predicate Device

Z-Medical's bone fixation devices are substantially equivalent to the following predicate devices, most recently cleared by the FDA:

Z-Medical Device	Predicate Device	510(k) Number	510(k) Holder
Z-Snap Off Screw	CHARLOTTE Snap-Off Screw	K050819	Wright Medical Technology
Z-Double Thread Compression Screw	Foot and Hand Motion System Synthes 3.0 mm Headless Compression Screw	K091118 K050636	NewClip Technics Synthes (USA)
Z-Guide wire	Orthopaedic Fixation Pins and Wires / Kirschner / Guide Wires	K100736	SMT Schilling Metalltechnik GmbH
Z-Staple	Compression Staple and Simple Staple MLI Modular Staples	K043059 K962705	Wright Medical Technology Medicine Lodge Inc.

4. Description of the Device

4.1. Z-Snap Off Screw

Main application of the Snap Off Screw is the forefoot surgery. The device is intended to connect bones or bone fragments. Especially in the classic "Weil"-osteotomy you can fix the two parts of bones with this kind of screw.

Material: ASTM F136 (Ti-6Al-4V ELI)
Length: 11 mm to 14 mm
Diameter: 2 mm

4.2. Z-Double Thread Compression Screw

The Double thread compression screw is mainly used in the forefoot surgery. Most common use is in the "Scarf"-osteotomy. They are cannulated to work with a guide wire and they are drilled in manually.

Material: ASTM F136 (Ti-6Al-4V ELI)
Length: 10 mm to 36 mm
Diameter: 3 and 4 mm

4.3. Z-Guide Wire

Guide wires are used in all fields of surgery. Main applications are: determine the correct position for e.g. screws or drills, or fixation of bones, fragments or instruments. They are usually put in by machine. Guide wires are also used to drill holes, e.g. to apply staples.

Material: ASTM F 138 (1.4441)
Length: 80 mm to 380 mm
Diameter: 0.7 mm to 6.35 mm
End Styles: Trocar
Type: Smooth

4.4. Z-Staple

Staples are implants for fixing bones or fragments. Z-Staples use the SnapOff-technology by Z-Medical. The distal end of the staple can be uses as drilling gauge as well as grip to put in the staple. After reaching the final position, the grip can be snapped off by moving sideways.

Material:	ASTM F136 (Ti-6Al-4V ELI)
Size:	8 mm to 25 mm
Method of insertion:	Staple inserter and SnapOff technique

5. Indications for Use

5.1. Z-Snap Off Screw

The Z-Medical SnapOff screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

5.2. Z-Double Compression Screw

The Z-Medical double thread compression screws are indicated for fixation of bone fractures or bone reconstruction. Examples included:

- Fixation of bone fragments or small bone fractures
- Fracture management in the foot and hand
- Arthrodesis in hand, foot or ankle surgery
- Mono or Bi-cortical osteotomies in the foot and hand

5.3. Z-Guide Wire

The Z-Medical's guide wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of implants into the skeletal system.

5.4. Z-Staple

The Z-Medical Staples are indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon. Examples included:

- Fixation of bone fragments or small bones fractures
- Fracture management in the foot and hand

6. Testing

Testing in order to help establish safety and effectiveness of Z-Medical's bone fixation devices has been performed accordingly and results are conforming to the respective requirements.

- Z-SnapOff: Torque test, break-off test, sideways stability test, maximum torque test
- Z-Double Compression Screw: Screw-in test, screw compression test, maximum torque test
- Z-Staple: ASTM F564-10 test, break-off test

7. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Z-Medical's bone fixation devices are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.

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

Z-Medical GmbH & Co. KG
% Mr. Alexander Henninger
Quality Manager
Gänsäcker 38
Tuttlingen, Baden-Wuerttemberg
Germany 78532

Letter Dated: November 7, 2012

Re: K121277
Trade/Device Name: Z-Snap Off Screw, Z-Double Thread Compression Screw, Z-Guide Wire, Z-Staple
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, HTY
Dated: October 25, 2012
Received: October 25, 2012

Dear Mr. Henninger:

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

K121277

Indications for Use Statement

Device Name:
Z-Snap Off Screw

Indications for Use:

The Z-Medical SnapOff screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

Prescription Use __YES___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K121277

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Indications for Use Statement

Device Name:
Z-Double Thread Compression Screw

Indications for Use:

The Z-Medical double thread compression screws are indicated for fixation of bone fractures or bone reconstruction. Examples included:

- Fixation of bone fragments or small bone fractures
- Fracture management in the foot and hand
- Arthrodesis in hand, foot or ankle surgery
- Mono or Bi-cortical osteotomies in the foot and hand

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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Indications for Use Statement

Device Name:
Z-Guide Wire

Indications for Use:

The Z-Medical's guide wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of implants into the skeletal system.

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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Indications for Use Statement

Device Name:
Z-Guide Staple

Indications for Use:

The Z-Medical Staples are indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon. Examples included:

- Fixation of bone fragments or small bones fractures
- Fracture management in the foot and hand

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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