K963937

Section 510(k)
Summary of Safety and
Effectiveness Information

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Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact

Company: **Northwest Precision Technologies**
812 West 6th Street, Suite 8144
The Dalles, OR. 97058
(541) 298-1088
(541) 296-1124 Fax

Contact: Dave Stinson
Owner
(541) 298-1088
(541) 296-1124 Fax

Establishment Registration Number: Pending

Device Name:

Trade Name: Northwest Precision Technologies
Ø6.5 mm Cannulated Cancellous Screw

Common Name: Cannulated Screw for Large Bones

Classification Name: Single / Multiple component metallic bone fixation appliances and accessories.

Classification Code: 87HRS

Substantially Equivalent Device(s)

1. Ace Medical Ø6.5 mm Cannulated Cancellous Screw
2. Alphatec Manufacturing Ø6.5 mm Cannulated Cancellous Screw

Device Description

The Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screw will be offered in two versions of an identical configuration. Both versions are identical with the exception of the overall thread length . One will be 16 mm and the second will be 32 mm in length. The length is measured from the distal tip up the shank. The screws will be fabricated from Titanium alloy Ti-6Al-4V, which complies with ASTM F-136. The device is of a single thread profile with a nominal major diameter

of Ø6.5 mm (.256 in.) and a nominal shank, or minor diameter, of 4.82 mm (.190 in.). The lengths offered at this time are 30 mm through 150 mm, in 5 mm increments. The overall length is measured from the underside of the head to the distal tip. The cannula, or inner diameter, is a nominal Ø3.26 mm (1285 in.) bore which will allow the use of a Ø2.5 mm Guide Pin ensuring safe and accurate placement of the screw. The "head" portion off the screw will embody an internal hexagon pocket to facilitate the insertion / extraction instrumentation. The distal tip embodies a self reaming / self tapping design. The self reaming feature incorporates three cutting teeth, while the self tapping is accomplished with three cutting flutes. Two cutting flutes will be located at the thread runout to the shank. They will be located at 180° to each other. These flutes are provided to ease extraction of the device. The self reaming and self tapping cannulated screws simplify the surgical procedure by allowing the surgeon to place the screw directly over the guide pin which is holding the reduced fracture in place. The efficiency of this simplified, time saving technique is well documented on other approved cannulated screw systems (Alphatec Manufacturing, Ace Medical, et., al).

Contraindications and Cautions

In the presence of ongoing sepsis and situations in which malignant primary or metastatic tumors or severe osteoporosis preclude bone support for the device. A comprehensive list of the indications, contraindications, adverse effects, warnings and precautions for this device may be found in the package insert. Be advised that only the package insert is to be considered definitive or accurate.

Instrumentation

We offer a complete line of instrumentation designed specifically to facilitate the placement and removal of our device(s). The current list includes:

1. Cannulated Hexdriver Shaft
2. Cannulated Countersink Shaft
3. Easy-Out Shaft
4. Power Pin Guide
5. Depth Gauge
6. 135° Drill Guide
7. Conical Handle(s)
8. T-Handle(s)
9. Washer
10. Guide Pin(s)
11. Sterilization Case(s)

Packaging:

The screws will be individually labeled and packaged in a container similar to the predicate devices noted. A polymer tube encapsulated with polymer caps at each end. The label will be affixed to the tube portion. Commercial grade shrink-wrap will encompass the entire package. This will reduce the possibility of the contamination and the label becoming unfixed.

Sterilization / Re-sterilization:

Sterilization must be accomplished by the end user of the device prior to use. High temperature steam sterilization with a cycle such as recommended by AORN or ACS is appropriate. This cycle should be performed with live steam at a temperature of at least 270° F. for a minimum of 15 minutes duration. Such a cycle has been validated by the manufacturer using the overkill method. Strict adherence to this sterility recommendation provides assurance of a reproducible 10^6 level kill.

Other sterility cycle temperatures and times or methods such as ETO gas may also be appropriate. The materials of the device will withstand virtually any steam or ETO gas cycle. However, individual hospitals and or physicians should validate any deviation from the manufacturer recommended sterility method and cycle times.

Testing / Analysis:

Device and system testing consisted of computer generated analysis that determined the bending strength and stiffness through a three point bend per ASTM E-8555. The results of all testing revealed that the Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screws are suitable for the indications noted and the anticipated conditions of use imposed on the device. Comparison test values for the Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screws and the Ace Medical and Alphatec Manufacturing Ø6.5 mm Cannulated Cancellous Screws were equivalent at all times.

Test reports demonstrated that the Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screws have been adequately designed to perform in a manner equivalent to that of the comparison device(s). Based on the testing, the Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screws are equal in performance to the Ace Medical and Alphatec Manufacturing Ø6.5 mm Cannulated Cancellous Screws

Equivalence:

For comparison purposes, no geometrically equivalent device exists. Therefore, the Ace Medical and Alphatec Manufacturing Ø6.5 mm Cannulated Cancellous Screws, a device of alike material ,design, and manufacturing method were selected for comparison.

The results of the three point bend test show that the Northwest Precision Technologies devices posses equivalent strength to the comparative devices.

Northwest Precision Technologies Ø6.5 mm Screws will be used on indications that have common usage with the Ace Ø6.5 mm Screws and the Alphatec Ø6.5 mm Screws. Maintaining the same indications for use provides two specific benefits. First the Northwest Precision Technologies is not promoting the safe use of the implant in any new or unfamiliar methods, so, the expected physiological loads and performance are well known. Clinical performance of similar screws used in these well known conditions is extensively reported in medical literature. Second, important device design characteristics have been refined over literally tens of thousands of uses with equivalent predicate devices. The clinical utility of a Ø6.5 mm Screw for treatment of such conditions is basic to orthopaedic surgery. Assuming appropriate materials and manufacturing conditions, the clinical performance of a new Ø6.5 mm Screw should be fairly predictable.

Therefore, based on the test results and indication demands, Northwest Precision Technologies believes that this device possesses sufficient strength and that parallel equivalency has been fully achieved.

Conclusion:

Our similar configuration to the predicated devices, validated by the testing results, and standardized manufacturing methods controlled by Good Manufacturing Practice regulations help to assure that the Northwest Precision Technologies Ø6.5 mm Cannulated Cancellous Screw is safe, effective, and substantially equivalent to the referenced comparison device(s).