510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

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III. DATE PREPARED	February 19, 2019
IV. DEVICE	
Name of Device	ATLAS™ Plating System
Common Name	Fixation Bone Screw System
Classification Name	21 CFR §888.3030 Single/multiple component metallic bone fixation appliances and accessories and 21 CFR §888.3040 Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Product Codes	HRS, HWC
Submission Type	Traditional 510(k)
V. PREDICATE DEVICE	<u>Primary Predicate</u> MINI MAXLOCK Extreme Plating System (K121437) <u>Additional Predicates</u> Wright ORTHOLOC 3Di LP Plates (K163044) Paragon28 Gorilla Plates (K140397) MaxLock Extreme Lateral TTC Plate (K132591) <u>Reference Device</u> Globus AUTOBAHN Nailing System (K171108)

VI. DEVICE DESCRIPTION

The ATLAS™ Plating System is a metallic plate and screw system for treatment and fixation of fractures, fusions and osteotomies of bones in the Foot, Ankle, Hand, and Wrist.

The plates are available in different geometries to accommodate different patient and bone anatomies. The plates are made from Titanium alloy (Ti-15Mo Alloy per ASTM F2066-18).

The screws are available in different diameters from Ø2.7mm to Ø5.5mm, non-locking or locking configurations with lengths ranging from 8mm to 60mm. All screws are manufactured from Titanium alloy (Ti-6Al-4V ELI per ASTM F136-13).

Implants are single use and the system is provided non-sterile.

VII. INDICATIONS FOR USE

The ATLAS™ Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies of small bones and bone fragments in adult and pediatric patients.

VIII. PREDICATE DEVICE COMPARISON

The documentation provided shows that the MiRus™ ATLAS™ Plating System is substantially equivalent to the predicate devices in intended use, indications for use, technological characteristics and labeling. The plate material and the predicate materials are made of Titanium alloys of different compositions to enhance strength.

IX. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- Mechanical testing for screws (ASTM F543)
- Mechanical testing for plates (ASTM F382)

X. CONCLUSONS

The MiRus™ ATLAS™ Plating System does not raise any new questions of safety or efficacy when compared to the predicate device(s). The ATLAS™ Plating System has demonstrated that it is substantially equivalent in mechanical performance, indications for use, intended use, technological characteristics, materials and labeling to legally marketed predicate devices.