510(k) Summary: ASSURE-T Anterior Cervical Plate

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Device Name: ASSURE® Anterior Cervical Plate System

Common Name: Anterior Cervical Plate System

Classification: Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ
Regulatory Class: II, Panel Code: 87

Primary Predicate: ASSURE® (K040721)

Additional Predicates: UNIFY® (K121049, K133567)
Aesculap ABC2 (K050813)

Purpose:
The purpose of this 510(k) is to request clearance for the ASSURE®-T Translational Anterior Cervical Plates, a modification of the predicate ASSURE® Anterior Cervical Plate System.

Device Description:
ASSURE®-T Translational Anterior Cervical Plates are anterior cervical plates that allow translation for intraoperative graft compression and postoperative settling. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7) using standard ASSURE® screws. The implants are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

Indications for Use:
The ASSURE® Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

Technological Characteristics:
ASSURE®-T implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Performance Data:
Mechanical testing (static and dynamic compression bending, and static torsion) was conducted in accordance with ASTM F1717 and, the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device.

Basis of Substantial Equivalence:
The ASSURE®-T Translational Anterior Cervical Plate has been found to be substantially equivalent to the predicates with respect to technological characteristics, performance, design, materials, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.