510(k) Summary: CROSSWAY™ Spinal Access System

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Device Name: CROSSWAY™ Spinal Access System

Common Name: Rigid Endoscope and Instrument Set

Classification: Per 21 CFR as follows:
§888.1100 Arthroscope
Product Code: HRX
Regulatory Class: II, Panel Code: 87

Primary Predicate: TransCorp Spinal Access System (K113352)

Reference Device: HAVEN Laminoplasty System (K171413)
QUARTEX Spinal System (K161591)

Purpose:
The purpose of this submission is to request clearance for sterile and modified CROSSWAY™ instruments.

Device Description:
The CROSSWAY™ Spinal Access System consists of instruments used for minimally invasive visualization and access to the anterior spine. The system includes various guides, sleeves, temporary fixation screws, drills, and general surgical instruments.

Indications for Use:
The CROSSWAY™ Spinal Access System is indicated for minimally invasive visualization and access to the anterior spine for assisting in various surgical procedures such as herniated disc repair, biopsy, or harvesting autogenous bone.

Performance Data:
Specification review and dimensional analysis demonstrate that the CROSSWAY™ instruments can be used in accordance with their indications.

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices.

Technological Characteristics:
Subject CROSSWAY™ instruments have similar technological characteristics with minor modifications compared to predicate CROSSWAY™ instruments including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
The CROSSWAY™ System has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided supports substantial equivalence to the predicate devices.