DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K183550

Device Name

Vitality® Spinal Fixation System

Indications for Use *(Describe)*

The Vitality® Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic sites), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality® Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality® System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality® System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Assembly of a spinal fixation construct using the Vitality® Spinal Fixation System may include additionally any Instinct Java® System hook, any APEX® System hook, or the Universal Clamp® (titanium). These direct-connect single point of fixation implants act in concert with the Vitality® System rods and implants to support its surgical indications for use.

In order to achieve additional levels of fixation, the Vitality® Spinal Fixation System rods may be connected to the Instinct Java® System (Ø5.5mm rod) or the Virage® OCT Spinal Fixation System (Ø3.5mm rod) with the corresponding Vitality® rod connectors. Refer to the Instinct Java® System and Virage® OCT Spinal Fixation System package inserts for instructions and indications for use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.