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)*
K253151

Device Name
Fule Interbody Fusion Cage Systems

Indications for Use *(Describe)*

Cervical Device

Cervical Spine (C2–T1): The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, at one level of the cervical spine with accompanying radicular symptoms. Patients should have undergone at least six weeks of non-operative treatment prior to surgery.

The implants are intended to facilitate fusion in the cervical spine (C2–T1) and are placed via an anterior cervical approach, using autogenous bone graft. When used in the cervical spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the cervical spine, such as anterior cervical plate and screw fixation systems.

Lumbar Devices

Lumbar Spine (L2–S1): The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, at one or two contiguous levels of the lumbar spine (L2–S1). Patients should have undergone at least six months of non-operative treatment prior to surgery.

These implants are intended to facilitate fusion in the lumbar spine and are placed via an oblique lumbar interbody fusion (OLIF), posterior lumbar interbody fusion (PLIF), or transforaminal lumbar interbody fusion (TLIF) approach, using autograft or allograft bone graft. When used in the lumbar spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the lumbar/lumbosacral spine, such as posterior pedicle screw and rod fixation systems.

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.

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