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)*
K190364

Device Name
CancelleX Porous Titanium Lumbar Interbody Device

Indications for Use *(Describe)*
CancelleX Porous Titanium Lumbar Interbody System devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non- fusion spinal surgery at the involved spinal level(s). The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. The device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the CancelleX device.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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