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)*
K211474

Device Name
Kleiner KG2 System

Indications for Use *(Describe)*
The KG2 implant is indicated for transforaminal and posterior interbody fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The KG2 implant is used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The interbody fusion devices are intended to be used with FDA-cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion 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.

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