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)*

K190598

Device Name
CROSSWAY™ Spinal Access System

Indications for Use *(Describe)*
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.

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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