004
Indications For Use

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)*
K182268

Device Name
EpiFaith Syringe (Luer Slip)
EpiFaith Syringe (NRFit)

Indications for Use *(Describe)*
EpiFaith Syringe is intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in the epidural space.

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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