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)*
K180753

Device Name
SafetyFix Easy Out System

Indications for Use *(Describe)*
The SafetyFix Easy Out System is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist.

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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