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)*

K190415

Device Name

ATLAS™ Plating System

Indications for Use *(Describe)*

The ATLAS™ Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies of small bones and bone fragments in adult and pediatric patients.

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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