DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

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K181639

Device Name
Panta 2 Nail Arthrodesis System

Indications for Use *(Describe)*

The Panta 2 Nail Arthrodesis System is intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Indications include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint.

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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