FDA 510(k) Premarket Notification

K170313 ARIX Ankle Distal Tibia System

CLEARED

Jul 27, 2017
176 days to decision

K170313 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k170313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 1, 2017
Decision date	Jul 27, 2017
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jeil Medical Corporation**
Location	Deer Field, IL, US
Contact	Sejin RYU
510(k) history	53 submissions · 53 cleared · 2002-2026