

K202815 PROPHECY Preoperative Navigation Alignment SystemMar 10, 2021
167 days to decisionK202815 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k202815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Sep 24, 2020
Decision date	Mar 10, 2021
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wrightmedicaltechnologyinc
Location	Arlington, TN, US
Contact	Paxia Her
510(k) history	302 submissions · 291 cleared · 1993-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026