

K100886 INBONE II TOTAL ANKLE REPLACEMENTAug 26, 2010
149 days to decisionK100886 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k100886/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Mar 30, 2010
Decision date	Aug 26, 2010
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100886/> 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 18, 2026