

K250037 Incompass Total Ankle SystemJun 20, 2025
163 days to decisionK250037 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k250037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Jan 8, 2025
Decision date	Jun 20, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wright Medical Technology, Inc. (Stryker)
Location	Memphis, TN, US
Contact	Antonio Ayala
510(k) history	2 submissions · 2 cleared · 2024-2025

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