FDA 510(k) Premarket Notification

K232144 Sterile Products of the APTUS System

CLEARED

Aug 18, 2023
30 days to decision

K232144 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k232144/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 19, 2023
Decision date	Aug 18, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medartis AG**
Location	San Diego, CA, US
Contact	Claudia De Santis
510(k) history	41 submissions · 41 cleared · 1999-2026

REGULATORY CONSULTANT

Consulting firm	**Medartis, Inc.**
Contact	Chelsea Kozior

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov