FDA 510(k) Premarket Notification

K260090 SMART Osteotomy System

CLEARED

Apr 10, 2026
88 days to decision

K260090 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k260090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 12, 2026
Decision date	Apr 10, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Actis Medical Pty., Ltd.**
Location	Torrensville, AU
Contact	Josh Balfour
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Aztech Regulatory & Quality, LLC**
Contact	Joseph Azary

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