

K181843 MLP Special Locking Bone Plate SystemMar 4, 2019
236 days to decisionK181843 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k181843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 11, 2018
Decision date	Mar 4, 2019
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maxxion Medical, LLC / Baumer SA
Location	Miami, FL, US
Contact	Bruno Baumer
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Medical Products International
Contact	Larry Petersen

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181843/> 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 June 28, 2026