

K203134 Hanger Cranial Band 3DJul 1, 2022
620 days to decisionK203134 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k203134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Oct 19, 2020
Decision date	Jul 1, 2022
Days to decision	620 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Symbion Logistics, LLC
Location	Tempe, AZ, US
Contact	Roselle Abad
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203134/> 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 26, 2026