

K252790 Digital ClarusScope System and Digital NeuroPEN SystemMay 26, 2026
266 days to decisionK252790 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k252790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Sep 2, 2025
Decision date	May 26, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clarus Medical, LLC
Location	Minneapolis, MN, US
Contact	Mark Brown
510(k) history	10 submissions · 10 cleared · 2001-2026

REGULATORY CONSULTANT

Consulting firm	Alan Vanhouten Biomedical Consultant
Contact	Alan VanHouten

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252790/>. 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 15, 2026