

K240535 Digital ClarusScope SystemApr 25, 2024
59 days to decisionK240535 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k240535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Feb 26, 2024
Decision date	Apr 25, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Digital NeuroPEN System

APPLICANT

Company	Clarus Medical, LLC
Location	Minneapolis, MN, US
Contact	Mark Brown
510(k) history	9 submissions · 9 cleared · 2001-2024

REGULATORY CONSULTANT

Consulting firm	Alan Vanhouten Biomedical Consulting
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)

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