FDA 510(k) Premarket Notification

K240535 Digital ClarusScope System

CLEARED

Apr 25, 2024
59 days to decision

K240535 · 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