

K192873 SX-One MicroKnife

Dec 20, 2019
73 days to decision

K192873 · Product code: **LXH** · Orthopedic
Source: <https://www.510kdatabase.net/k192873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Manual Surgical Instrument (LXH)
Date received	Oct 8, 2019
Decision date	Dec 20, 2019
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonex Health, Inc.
Location	Rochester, MN, US
Contact	Aaron Keenan
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Keri NG Consulting
Contact	Keri Ng

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