

K193608 EBERLE Shaver System C3 and AccessoriesJan 15, 2021
386 days to decisionK193608 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k193608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Dec 26, 2019
Decision date	Jan 15, 2021
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eberle GmbH & Co. KG
Location	Wurmberg, DE
Contact	Udo Schniebs
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Visamed GmbH
Contact	Arne Briest

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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