

K211297 SMARTRELEASE Endoscopic Soft Tissue Release System

Jun 24, 2021
57 days to decisionK211297 · Product code: **HRX** · General Hospital
Source: <https://www.510kdatabase.net/k211297/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 28, 2021
Decision date	Jun 24, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microaire Surgical Instruments
Location	Charlottesville, VA, US
Contact	Glenn Gerstenfeld
510(k) history	3 submissions · 3 cleared · 2020-2023

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Device record: <https://www.510kdatabase.net/k211297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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