

**K181819 SMARTRELEASE Endoscopic Soft Tissue Release System**Nov 6, 2018  
120 days to decisionK181819 · Product code: **HRX** · General Hospital  
Source: <https://www.510kdatabase.net/k181819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 9, 2018
Decision date	Nov 6, 2018
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Microaire Surgical Instruments, LLC</b>
Location	Chesterfield, VA, US
Contact	Glenn Gerstenfeld
Website	<a href="https://www.microaire.com">https://www.microaire.com</a>
510(k) history	9 submissions · 9 cleared · 2012-2025

Microaire Surgical Instruments, LLC designs and manufactures surgical devices for General & Plastic Surgery and related specialties. The company operates with a manufacturing facility in Chesterfield, US, and serves surgeons globally through an established distribution network. Microaire has received FDA 510(k) clearances from total submissions since 2012. General & Plastic Surgery devices represent the dominant focus, accounting for 78% of regulatory submissions. The company remains active, with its most recent clearance in 2025. The company's product portfolio centers o...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k181819/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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