

**K191345 Pegasus System**Jul 17, 2019  
58 days to decisionK191345 · Product code: **HRX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	May 20, 2019
Decision date	Jul 17, 2019
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>A.M. Surgical, Inc.</b>
Location	Great Neck, NY, US
Contact	Vincent Pascale
510(k) history	6 submissions · 6 cleared · 1998-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191345/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 25, 2026