

K151017 JMS Harmony A.V. Fistula Needle SetMay 13, 2015
27 days to decisionK151017 · Product code: **FIE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k151017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Fistula (FIE)
Date received	Apr 16, 2015
Decision date	May 13, 2015
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	JMS North America Corporation
Location	Crofton, MD, US
Contact	SHO HOSOKI
510(k) history	9 submissions · 9 cleared · 2011-2025

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