

K161255 meso-relle (AAL34, AAL36, AM30G)Jan 19, 2017
261 days to decisionK161255 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k161255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 3, 2016
Decision date	Jan 19, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotekne Srl
Location	Casalecchio Di Reno, IT
Contact	Fabio Tassi
510(k) history	1 submissions · 1 cleared · 2017-2017

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