

K160575 CareSens Pen Needle, Softip Pen NeedleSep 7, 2016
190 days to decisionK160575 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k160575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 1, 2016
Decision date	Sep 7, 2016
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Yidobio, Inc.
Location	Hwaseong-Si, KR
Contact	KYUNG HEE YOON
510(k) history	1 submissions · 1 cleared · 2016-2016

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