

K160316 SemiCut Semi-automatic Biopsy Needle, Themy Automatic Disposable Biopsy Device, Palium Automatic Reusable Biopsy Device, EasyCut Semi-automatic Biopsy Needle, MDL Biopsy and Coaxial Introducer NeedlesOct 27, 2016
265 days to decisionK160316 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 5, 2016
Decision date	Oct 27, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	M.D.L. S.R.L.
Location	Delebio (So), IT
Contact	Marcello Dell'Oca
510(k) history	1 submissions · 1 cleared · 2016-2016

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