

K181803 Medax Biopsy Systems IIIOct 18, 2018
105 days to decisionK181803 · Product code: **KNW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 5, 2018
Decision date	Oct 18, 2018
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medax Srl Unipersonale
Location	Poggio Rusco, IT
Contact	Stefano Cavalieri
510(k) history	5 submissions · 5 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	Coronati Consulting Srl
Contact	Serena Coronati

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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