

K192101 Medone Ultra, MedextraApr 2, 2020
241 days to decisionK192101 · Product code: **KNW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 5, 2019
Decision date	Apr 2, 2020
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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	Gemarmed S.R.L
Contact	Stefano Cavalieri

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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