FDA 510(k) Premarket Notification

K192101 Medone Ultra, Medextra

CLEARED

Apr 2, 2020
241 days to decision

K192101 · 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