FDA 510(k) Premarket Notification

K181803 Medax Biopsy Systems III

CLEARED

Oct 18, 2018
105 days to decision

K181803 · Product code: **KNW** · General & Plastic Surgery
Source: 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