

# K192099 MED-I Bone Marrow Aspiration Needle, MED-S Bone Marrow Aspiration Needle, MED-L Bone Marrow Biopsy and Aspiration System, MED-B Bone Marrow Biopsy System, MED-J Bone Marrow Biopsy and Aspiration System

Apr 2, 2020  
241 days to decision

K192099 · Product code: **KNW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k192099/>

## SUBMISSION DETAILS

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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

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Company	<b>Medax Srl Unipersonale</b>
Location	Poggio Rusco, IT
Contact	Stefano Cavaliere
510(k) history	5 submissions · 5 cleared · 2015-2020

## REGULATORY CONSULTANT

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Consulting firm	<b>Garmed S.R.L</b>
Contact	Stefano Cavaliere

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192099/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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