

**K223300 Estacore-Pro Automatic Biopsy Needle, Geotek Semiautomatic Biopsy Needle, Maxicore-M Automatic Biopsy Gun Needle, Maxicore-M Automatic Biopsy Needle and Instrument**Apr 21, 2023  
176 days to decisionK223300 · Product code: **KNW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k223300/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Oct 27, 2022
Decision date	Apr 21, 2023
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Geotek Medikal Ltd Sti</b>
Location	Ankara, TR
Contact	Latif Iba
510(k) history	2 submissions · 2 cleared · 2017-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Licensale, Inc.</b>
Contact	Raymond Kelly

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/k223300/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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