

**K212158 HydroMARK Breast Biopsy Site Marker**Apr 21, 2022  
283 days to decisionK212158 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jul 12, 2021
Decision date	Apr 21, 2022
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Devicor Medical Products, Inc.</b>
Location	Cincinnati, OH, US
Contact	Diane Sung
510(k) history	16 submissions · 16 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212158/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026