

K203097 HydroMARK Breast Biopsy Site MarkersDec 16, 2020
63 days to decisionK203097 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Oct 14, 2020
Decision date	Dec 16, 2020
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Devicor Medical Products, Inc.
Location	Cincinnati, OH, US
Contact	Rhonda M. Kops
510(k) history	16 submissions · 16 cleared · 2012-2026

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