

**K253761 HydroMARK™ Plus Breast Biopsy Site Marker
(Dragonfly Shape)**

Jan 23, 2026
59 days to decision

K253761 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253761/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Nov 25, 2025
Decision date	Jan 23, 2026
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HydroMARK™ Plus Breast Biopsy Site Marker (Hummingbird Shape)

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253761/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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