

**K090501 BIOPSY SCIENCES HYDROMARK BREAST BIOPSY
SITE MARKER, MODELS 4005-02-15-T1, 4005-02-15-S1,
4005-03-15-T1, 4005-03-15-S1**

Mar 5, 2009
8 days to decision

K090501 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k090501/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Feb 25, 2009
Decision date	Mar 5, 2009
Days to decision	8 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biopsy Sciences, LLC
Location	Yorba Linda, CA, US
Contact	SHARON ROCKWELL
510(k) history	8 submissions · 8 cleared · 2002-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090501/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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