

**K121113 BIOPSY SCIENCES, INC. HYDROMARK BREST BIOSY
SITE MARKER**Jul 12, 2012
91 days to decisionK121113 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k121113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Apr 12, 2012
Decision date	Jul 12, 2012
Days to decision	91 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.netDevice record: <https://www.510kdatabase.net/k121113/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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