

K083006 BIOPSY SCIENCES, INC., HYDROMARK BREAST BIOPSY SITE MARKER

Feb 9, 2009
124 days to decision

K083006 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k083006/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Oct 8, 2008
Decision date	Feb 9, 2009
Days to decision	124 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/k083006/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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