

**K163667 RFID Localization System- Localizer Reader, RFID
Localization System- Localizer Surgical Probe, RFID
Localization System- Localizer Surgical Probe (5 pack), RFID
Localization System- Tag Applicator, RFID Localization System
-Tag Applicator (10 pack)**

Apr 28, 2017
122 days to decision

K163667 · Product code: **PBY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163667/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Tissue Marker (PBY)
Date received	Dec 27, 2016
Decision date	Apr 28, 2017
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Health Beacons, Inc.
Location	Concord, MA, US
Contact	NANCY CONFREY
510(k) history	4 submissions · 4 cleared · 2017-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163667/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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