

**K193189 RFID Localization System**May 6, 2020  
169 days to decisionK193189 · Product code: **NEU** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k193189/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Nov 19, 2019
Decision date	May 6, 2020
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Health Beacons, Inc.</b>
Location	Concord, MA, US
Contact	Nancy Confrey
510(k) history	4 submissions · 4 cleared · 2017-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>R&amp;Q Solutions</b>
Contact	Felicia Hosey

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193189/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026