

K190932 RFID Localization SystemSep 13, 2019
156 days to decisionK190932 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Apr 10, 2019
Decision date	Sep 13, 2019
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	R&Q Solutions
Contact	Carol Vierling

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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