

K181692 5cm Tag Applicator, 7cm Tag Applicator, 10 cm Tag Applicator, 5 cm Tag Applicator (10 pack), 7cm Tag Applicator (10 pack), 10cm Tag Applicator (10 pack), LOCALizer Surgical Probe, LOCALizer Surgical Probe (5 pack)Sep 25, 2018
90 days to decisionK181692 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181692/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jun 27, 2018
Decision date	Sep 25, 2018
Days to decision	90 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	Regulatory and Quality Solutions, LLC
Contact	Felicia Hosey

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

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