FDA 510(k) Premarket Notification

K200652 Lollipop BiteBlock

CLEARED

Jul 6, 2020
116 days to decision

K200652 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k200652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 12, 2020
Decision date	Jul 6, 2020
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Radtec Medical Devices, Inc.**
Location	San Carlos, CA, US
Contact	Ross Holman
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Michelle Rubin-Onur

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