FDA 510(k) Premarket Notification

K191801 PROBEAT-CR

CLEARED

Sep 13, 2019
72 days to decision

K191801 · Product code: **LHN** · Radiology
Source: https://www.510kdatabase.net/k191801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jul 3, 2019
Decision date	Sep 13, 2019
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hitachi , Ltd.**
Location	Washington, Dc, DC, US
Contact	Tomoyuki Seino
510(k) history	8 submissions · 8 cleared · 2006-2020

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Jonathan Kahan

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