

K181676 Mini Ridge Filter and auxiliary functions for PROBEAT-V

Aug 15, 2018
51 days to decision

K181676 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k181676/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jun 25, 2018
Decision date	Aug 15, 2018
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Ltd. Healthcare Hitachi Works
Location	Hitachi, JP
Contact	Tomoyuki Seino
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181676/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026