

K152224 Proton Therapy System - Proteus 235 (Proteus One, Proteus Plus, Proteus TK2)Aug 9, 2016
368 days to decisionK152224 · Product code: LHN · Radiology
Source: <https://www.510kdatabase.net/k152224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Aug 7, 2015
Decision date	Aug 9, 2016
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ion Beam Application S.A.
Location	Louvain-La-Neuve, BE
Contact	ANNE-SOPHIE GRELL
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152224/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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