

K183606 Delta4 Phantom+ MR (PMMA), Delta4 Phantom+ MR (PW)Apr 8, 2019
103 days to decisionK183606 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k183606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 26, 2018
Decision date	Apr 8, 2019
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scandidos AB
Location	Uppsala, SE
Contact	Thomas Matzen
510(k) history	5 submissions · 5 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183606/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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