

K031634 OMNIPRO I'MRTAug 29, 2003
94 days to decisionK031634 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k031634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 27, 2003
Decision date	Aug 29, 2003
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wellhofer Dosimetrie
Location	Uppsala, SE
Contact	THOMAS MATZEN
510(k) history	2 submissions · 2 cleared · 2003-2003

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