

K954861 BRAINLAB CT/X-RAY LOCALIZERAug 5, 1996
287 days to decisionK954861 · Product code: **IYE** · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 23, 1995
Decision date	Aug 5, 1996
Days to decision	287 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Brainlab Med. Computersysteme GmbH
Location	Troy, NY, US
Contact	MICHAEL BERTRAM
510(k) history	5 submissions · 5 cleared · 1994-1997

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