

K903805 AMICI XENON ADMINISTRATION SETJan 14, 1991
152 days to decisionK903805 · Product code: IYT · Radiology
Source: <https://www.510kdatabase.net/k903805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Rebreathing, Radionuclide (IYT)
Date received	Aug 15, 1990
Decision date	Jan 14, 1991
Days to decision	152 days
Third-party review	No

APPLICANT

Company	Amici, Inc.
Location	Royersford, PA, US
Contact	MICHAEL BONO
510(k) history	8 submissions · 8 cleared · 1987-2007

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