

**K903694 AMICI TRU-FIT SOFT PLASTIC MOUTHPIECE**Oct 3, 1990  
49 days to decisionK903694 · Product code: IYT · Radiology  
Source: <https://www.510kdatabase.net/k903694/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Rebreathing, Radionuclide (IYT)
Date received	Aug 15, 1990
Decision date	Oct 3, 1990
Days to decision	49 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k903694/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026