

**K013038 SAFE MAXI HOLLOW FIBER OXYGENATOR, MODEL 016010**Aug 14, 2002  
338 days to decisionK013038 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k013038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 10, 2001
Decision date	Aug 14, 2002
Days to decision	338 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Polystan A/S</b>
Location	Denmark, DK
Contact	DANA OLSEN
510(k) history	6 submissions · 6 cleared · 1991-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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