

**K002847 INTRODUCER WITH DISTAL RADIOPAQUE MARKER  
BAND, MODEL OR-4926XX**May 31, 2001  
260 days to decisionK002847 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k002847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Introducer, Catheter (DYB)
Date received	Sep 13, 2000
Decision date	May 31, 2001
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maxxim Medical</b>
Location	Arlington, TX, US
Contact	GAIL DOHERTY
510(k) history	26 submissions · 25 cleared · 1994-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002847/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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