

**K922972 MODELS 438-05 AND 435-05 IMPLANTABLE PACING  
LEAD**Jan 22, 1993  
217 days to decisionK922972 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k922972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jun 19, 1992
Decision date	Jan 22, 1993
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intermedics, Inc.</b>
Location	Mchenry, IL, US
Contact	ANTHONY FONSECA
510(k) history	211 submissions · 201 cleared · 1977-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922972/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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