

**K031785 MACROPORE CARDIO-WRAP (TS)**Sep 4, 2003  
86 days to decisionK031785 · Product code: **OMH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031785/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pericardial Patch To Facilitate Revision Surgeries (OMH)
Date received	Jun 10, 2003
Decision date	Sep 4, 2003
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Macropore Biosurgery, Inc.</b>
Location	San Diego, CA, US
Contact	KENNETH K KLEINHENZ
510(k) history	17 submissions · 16 cleared · 2000-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031785/> 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 20, 2026