

**K071065 ORTHADAPT BIOIMPLANT**May 4, 2007  
18 days to decisionK071065 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k071065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Apr 16, 2007
Decision date	May 4, 2007
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pegasus Biologics, Inc.</b>
Location	Irvine, CA, US
Contact	PAMELA MISAJON
510(k) history	5 submissions · 5 cleared · 2005-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071065/> 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 June 23, 2026