

**K082746 ULTRA IABP CATHETER KIT, MODELS IMU7F-40,  
IMU7F-35, IMU7F-30, IMU7F-25, IMU7F-20**Jan 12, 2009  
115 days to decisionK082746 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082746/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Sep 19, 2008
Decision date	Jan 12, 2009
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Insightra Medical, Inc.</b>
Location	Irvine, CA, US
Contact	TOM COLONNA
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082746/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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