

**K971628 SOMANETICS INVOS 3100A CEREBRAL OXIMETER (INVOS)**

Oct 10, 1997  
161 days to decision

K971628 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k971628/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 2, 1997
Decision date	Oct 10, 1997
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somanetics Corp.</b>
Location	Troy, MI, US
Contact	RONALD A WIDMAN
510(k) history	12 submissions · 12 cleared · 1990-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k971628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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