

**K021955 TRUTRAK PLUS ENHANCEMENTS TO THE DATEX-OHMEDA 3800 SERIES & 3900 SERIES OXIMETERS & ACCESSORIES**Oct 8, 2002  
116 days to decisionK021955 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k021955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Jun 14, 2002
Decision date	Oct 8, 2002
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datex-Ohmeda, Inc.</b>
Location	Madison, WI, US
Contact	MICHAEL A CHILBERT
510(k) history	60 submissions · 60 cleared · 1998-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021955/> 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 24, 2026