

K160582 WiCapSep 2, 2016
185 days to decisionK160582 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k160582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oximeter (DQA)
Date received	Mar 1, 2016
Decision date	Sep 2, 2016
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Athena Gtx
Location	Des Moines, IA, US
Contact	Sean Mahoney
510(k) history	7 submissions · 7 cleared · 2010-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160582/> Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026