

**K202433 Aqueduct 200 Cervical Dilation Balloon Catheter**Oct 15, 2021  
416 days to decisionK202433 · Product code: **PON** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Balloon, Dilation Of Cervical Canal (PON)
Date received	Aug 25, 2020
Decision date	Oct 15, 2021
Days to decision	416 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gtimd, LLC</b>
Location	Amherst, NH, US
Contact	Eran Levit
510(k) history	3 submissions · 3 cleared · 2016-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202433/> 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 26, 2026