FDA 510(k) Premarket Notification

K202433 Aqueduct 200 Cervical Dilation Balloon Catheter

CLEARED

Oct 15, 2021
416 days to decision

K202433 · Product code: **PON** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k202433/

SUBMISSION DETAILS

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

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