

K152628 Pulse H20h!Jul 11, 2016
300 days to decisionK152628 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k152628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Sep 15, 2015
Decision date	Jul 11, 2016
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Toaster Labs, Inc.
Location	Seattle, WA, US
Contact	AMY C. BUCKALTER
510(k) history	2 submissions · 2 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152628/> 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 2, 2026