FDA 510(k) Premarket Notification

CLEARED

K192203 JO for Him H2O Gel Original Personal Lubricant

Feb 10, 2020
180 days to decision

K192203 · Product code: **NUC** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k192203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Aug 14, 2019
Decision date	Feb 10, 2020
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**United Consortium**
Location	Valencia, CA, US
Contact	Stephanie Morris
510(k) history	14 submissions · 14 cleared · 2014-2020

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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