FDA 510(k) Premarket Notification

K172203 CryoDose TA OTC, Mist Spray, CryoDose TA OTC, Stream Spray

CLEARED

Oct 18, 2017
89 days to decision

K172203 · Product code: **MLY** · Physical Medicine
Source: https://www.510kdatabase.net/k172203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vapocoolant Device (MLY)
Date received	Jul 21, 2017
Decision date	Oct 18, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nuance Medical, LLC**
Location	Carlsbad, CA, US
Contact	Marc Lieberman
510(k) history	6 submissions · 6 cleared · 2013-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k172203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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