

K190161 Ethyl Chloride Medium Jet Stream, Ethyl Chloride Fine Pinpoint spray, Ethyl Chloride Mist, Ethyl Chloride Accustream 360* Medium Spray, Ethyl Chloride Accustream 360* Fine Spray

May 7, 2019
97 days to decision

K190161 · Product code: **MLY** · Physical Medicine
Source: <https://www.510kdatabase.net/k190161/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vapocoolant Device (MLY)
Date received	Jan 30, 2019
Decision date	May 7, 2019
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gebauer Company
Location	Cleveland, OH, US
Contact	Brittney Cooper
510(k) history	2 submissions · 2 cleared · 2017-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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