

K151461 Hybernite RTMar 24, 2016
297 days to decisionK151461 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k151461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	Jun 1, 2015
Decision date	Mar 24, 2016
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Plastiflex Group NV
Location	Claremont, NH, US
Contact	RAF VAN ROY
510(k) history	2 submissions · 2 cleared · 2010-2016

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