

**K100104 HYBERNITE RAINOUT CONTROL SYSTEM**Apr 14, 2010  
91 days to decisionK100104 · Product code: **BZE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k100104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	Jan 13, 2010
Decision date	Apr 14, 2010
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Plastiflex Group NV</b>
Location	Claremont, NH, US
Contact	WILLIAM GREENROSE
510(k) history	2 submissions · 2 cleared · 2010-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100104/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026