

**K080966 HYPER-BOX TOPICAL WOUND OXYGEN SYSTEM**Aug 6, 2008  
124 days to decisionK080966 · Product code: **KPJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k080966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Oxygen, Topical, Extremity (KPJ)
Date received	Apr 4, 2008
Decision date	Aug 6, 2008
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aoti , Ltd.</b>
Location	Galway, IE
Contact	ROBBIE WALSH
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080966/> 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 June 24, 2026