

**K102971 FREEDOMAIRE III SURGICAL HELMET SYSTEM  
MODEL 10322STK**Feb 23, 2011  
140 days to decisionK102971 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k102971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Oct 6, 2010
Decision date	Feb 23, 2011
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Microtek Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	THOMAS B BONNER, JR.
510(k) history	24 submissions · 24 cleared · 1984-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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