

**K080117 PATIENT ISOLATION UNIT, MODEL G019-1000**Jan 30, 2009  
379 days to decisionK080117 · Product code: **LGM** · General Hospital  
Source: <https://www.510kdatabase.net/k080117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Patient Isolation (LGM)
Date received	Jan 17, 2008
Decision date	Jan 30, 2009
Days to decision	379 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gentex Corporation</b>
Location	Mchenry, IL, US
Contact	BARRY SHOPE
510(k) history	3 submissions · 3 cleared · 1977-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080117/> 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 23, 2026