

**K100451 GAMCATH HIGH FLOW DOLPHIN MS-GDHC-1315 A**Dec 21, 2010  
307 days to decisionK100451 · Product code: **MPB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k100451/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Feb 17, 2010
Decision date	Dec 21, 2010
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary
Other names	AND MS-GDHC-1315J A, GAMCATH HIGH FLOW DOLPHIN MS-GDHC-1320 A; AND MS-GDHC-132

**APPLICANT**

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Company	<b>Gambro Renal Products, Inc.</b>
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100451/> 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 7, 2026