

K040301 GAMCATH HIGH FLOW CATHETER, REF: GDHK 13XX

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Nov 1, 2004
266 days to decision

K040301 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k040301/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Feb 9, 2004
Decision date	Nov 1, 2004
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	THOMAS B DOWELL
510(k) history	24 submissions · 23 cleared · 2000-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k040301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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