

**K063795 GUARDIANCATHETER-URINARY DRAINAGE
CATHETER**

Mar 5, 2007
73 days to decision

K063795 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k063795/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Dec 22, 2006
Decision date	Mar 5, 2007
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Marian Medical, Inc.
Location	Destin, FL, US
Contact	SANDRA WINKLER
510(k) history	4 submissions · 4 cleared · 2005-2007

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k063795/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026