

**K032710 CLOSED SYSTEM INTERMITTENT CATHETERIZATION
KIT**Jan 9, 2004
129 days to decisionK032710 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k032710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Sep 2, 2003
Decision date	Jan 9, 2004
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apogee Medical, Inc.
Location	Youngsville, NC, US
Contact	DIANE N PEPER
510(k) history	2 submissions · 2 cleared · 2001-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032710/>. 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 30, 2026