

K001583 ISLAND BIOSURGICAL BNS KIT #3Jul 13, 2000
52 days to decisionK001583 · Product code: **KOD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k001583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	May 22, 2000
Decision date	Jul 13, 2000
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Island Biosurgical, LLC
Location	Mercer Island, WA, US
Contact	HUNTER A MCKAY
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001583/> 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