

**K982042 ISLAND BIOSURGICAL BLADDER NECK BOLSTR
MODEL IBIBOL.002**Sep 8, 1998
90 days to decisionK982042 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k982042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jun 10, 1998
Decision date	Sep 8, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Island Biosurgical, Inc.
Location	Mercer Island, WA, US
Contact	HUNTER A MCKAY
510(k) history	3 submissions · 3 cleared · 1996-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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