

**K960101 ISLAND BIOSURGICAL BOLSTER**Dec 16, 1996  
340 days to decisionK960101 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k960101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jan 11, 1996
Decision date	Dec 16, 1996
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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