

**K904646 BCI-100 FECAL INCONTINENCE SYSTEM**Mar 19, 1991  
159 days to decisionK904646 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k904646/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Oct 11, 1990
Decision date	Mar 19, 1991
Days to decision	159 days
Third-party review	No

**APPLICANT**

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Company	<b>Biocare Intl.</b>
Location	Wantagh, NY, US
Contact	STEVEN H REICHMAN
510(k) history	1 submissions · 1 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904646/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026