

K955439 THE REEL THING (MODIFICATION)Dec 26, 1995
43 days to decisionK955439 · Product code: **GBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k955439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Irrigation (GBX)
Date received	Nov 13, 1995
Decision date	Dec 26, 1995
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biomedical Devices, Inc.
Location	Mchenry, IL, US
Contact	NICK HERBERT
510(k) history	7 submissions · 7 cleared · 1983-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955439/> 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 May 22, 2026