FDA 510(k) Premarket Notification

K043515 GRAFTSAVER

CLEARED

Mar 31, 2005
101 days to decision

K043515 · Product code: **GBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k043515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Irrigation (GBX)
Date received	Dec 20, 2004
Decision date	Mar 31, 2005
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vescare, Inc.**
Location	Billerica, MA, US
Contact	DAVID WALSH
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k043515/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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