

**K002803 THE O'NEIL STERILE FIELD URINARY
CATHETER KIT**Dec 27, 2000
110 days to decisionK002803 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k002803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Sep 8, 2000
Decision date	Dec 27, 2000
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Go Medical Industries Pty. , Ltd.
Location	Walker, MI, US
Contact	GEORGE O'NEIL
510(k) history	11 submissions · 11 cleared · 1984-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002803/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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