

**K011055 THE O'NEIL STERILE FIELD URINARY
CATHETER KIT WITH PREP PADS**Jun 6, 2001
61 days to decisionK011055 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Apr 6, 2001
Decision date	Jun 6, 2001
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

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/k011055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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