

K945806 SILICATH ALL SILICONE FOLEY CATHETERMar 21, 1995
113 days to decisionK945806 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k945806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 28, 1994
Decision date	Mar 21, 1995
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Unomedical Sdn Bhd
Location	Sungai Petani, Kedah, MY
Contact	LIM K KANG
510(k) history	9 submissions · 9 cleared · 1995-1998

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