FDA 510(k) Premarket Notification

K920451 ENDOTEK ULTRA SYSTEM

CLEARED

Sep 17, 1992
226 days to decision

K920451 · Product code: **FAP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k920451/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Feb 4, 1992
Decision date	Sep 17, 1992
Days to decision	226 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Surgitek**
Location	Mchenry, IL, US
Contact	WILLIAM H DUFFELL
510(k) history	29 submissions · 28 cleared · 1983-1995