FDA 510(k) Premarket Notification

K011325 MEDIFIX URETEROSCOPE

CLEARED

Jul 25, 2001
85 days to decision

K011325 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k011325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	May 1, 2001
Decision date	Jul 25, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medifix, Inc.**
Location	Morton Grove, IL, US
Contact	GEORGE ALBULESCU
510(k) history	4 submissions · 4 cleared · 1999-2001