FDA 510(k) Premarket Notification

K103326 MULTIPLE BIOPSY SYSTEM

CLEARED

Apr 6, 2011
145 days to decision

K103326 · Product code: **FCK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k103326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy, Suction (FCK)
Date received	Nov 12, 2010
Decision date	Apr 6, 2011
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**United States Endoscopy Group, Inc.**
Location	Mentor, OH, US
Contact	CARROLL L MARTIN
510(k) history	94 submissions · 92 cleared · 1991-2020