FDA 510(k) Premarket Notification

K083802 SONOTIP II 25-GAUGE ULTRASOUND NEEDLE SYSTEM, MODELS GUS-01-18-025 AND GUS-01-27-025

CLEARED

Mar 20, 2009
88 days to decision

K083802 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k083802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Dec 22, 2008
Decision date	Mar 20, 2009
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medi-Globe Corporation**
Location	Tempe, AZ, US
Contact	SCOTT KARLER
510(k) history	7 submissions · 7 cleared · 2006-2016