FDA 510(k) Premarket Notification

K892071 GENERAL (BIOPSY) NEEDLE GUIDE KIT, STERILE

CLEARED

Aug 8, 1989
130 days to decision

K892071 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k892071/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 31, 1989
Decision date	Aug 8, 1989
Days to decision	130 days
Third-party review	No

APPLICANT

Company	**Amedic USA**
Location	Phoenix, AZ, US
Contact	ANDERS WEILANDT
510(k) history	10 submissions · 10 cleared · 1987-1990