FDA 510(k) Premarket Notification

K963825 AUTO SUTURE* ABBI* SYSTEM

CLEARED

Dec 20, 1996
87 days to decision

K963825 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k963825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 24, 1996
Decision date	Dec 20, 1996
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**United States Surgical, A Division of Tyco Healthc**
Location	Mchenry, IL, US
Contact	CURTIS RAYMOND
510(k) history	218 submissions · 200 cleared · 1977-2007