FDA 510(k) Premarket Notification

K811965 VISITEC NEEDLE RANGE (GASTERUROLOGY)

CLEARED

Aug 25, 1981
46 days to decision

K811965 · Product code: **FHR** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k811965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Gastro-urology (FHR)
Date received	Jul 10, 1981
Decision date	Aug 25, 1981
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Visitec Co.**
Location	Walker, MI, US
510(k) history	49 submissions · 49 cleared · 1979-1995