FDA 510(k) Premarket Notification

K965093 OMNITECH RESECTOSCOPE ROLLER ELECTRODE

CLEARED

Mar 19, 1997
90 days to decision

K965093 · Product code: **FAS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k965093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Dec 19, 1996
Decision date	Mar 19, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omnitech Systems, Inc.**
Location	Valparaiso, IN, US
Contact	GENE S ESTILL
510(k) history	6 submissions · 6 cleared · 1997-2016