FDA 510(k) Premarket Notification

K973158 ORATEC INTERVENTIONS MODEL ORASTAT MONOPOLAR CAUTERY DEVICE

CLEARED

Nov 5, 1997
75 days to decision

K973158 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k973158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 22, 1997
Decision date	Nov 5, 1997
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Oratec Interventions, Inc.**
Location	Mountain View, CA, US
Contact	MICHAEL KWAN
510(k) history	24 submissions · 24 cleared · 1995-2002