FDA 510(k) Premarket Notification

K072394 PORTRAIT STAND-OFF

CLEARED

Sep 12, 2007
16 days to decision

K072394 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 27, 2007
Decision date	Sep 12, 2007
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rhytec Incorporated**
Location	North Reading, MA, US
Contact	Robert Zoletti
510(k) history	5 submissions · 5 cleared · 2006-2008