FDA 510(k) Premarket Notification

K962605 PRO-GUARD DOUBLE-DUTY STERILIZATION WRAP (SINGLE USE)

CLEARED

Mar 11, 1997
252 days to decision

K962605 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k962605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 2, 1996
Decision date	Mar 11, 1997
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Surgicot, Inc.**
Location	Mchenry, IL, US
Contact	BEN B BROCK
510(k) history	19 submissions · 19 cleared · 1977-1997