FDA 510(k) Premarket Notification

K885019 BEMIS STERILE-CASE FOR USE W/ETHYLENE OXIDE STERI.

CLEARED

Jan 25, 1989
57 days to decision

K885019 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k885019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Nov 29, 1988
Decision date	Jan 25, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	**Bemis Health Care**
Location	Mchenry, IL, US
Contact	JANE M TURNER
510(k) history	12 submissions · 12 cleared · 1976-1989