FDA 510(k) Premarket Notification

K802919 ISO-BAC INSTRUMENT WRAP

CLEARED

Feb 2, 1981
76 days to decision

K802919 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k802919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Nov 18, 1980
Decision date	Feb 2, 1981
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**American Convertors Div., American Pharmaseal**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1980-1984