FDA 510(k) Premarket Notification

K832594 PRE-BYPASS FILTER #EC-PBF SERIES

CLEARED

Sep 20, 1983
49 days to decision

K832594 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k832594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Aug 2, 1983
Decision date	Sep 20, 1983
Days to decision	49 days
Third-party review	No

APPLICANT

Company	**Gish Biomedical, Inc.**
Location	Mchenry, IL, US
510(k) history	75 submissions · 75 cleared · 1983-2009