FDA 510(k) Premarket Notification

K991549 EMBOSPHERE MICROSPHERES

CLEARED

Apr 26, 2000
359 days to decision

K991549 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k991549/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	May 3, 1999
Decision date	Apr 26, 2000
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosphere Medical**
Location	Rockland, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	2 submissions · 2 cleared · 2000-2001