FDA 510(k) Premarket Notification

K002795 MODEL HYBRID 3200 MONOPLACE, HYPERBARIC THERAPY SYSTEMS

CLEARED

Dec 6, 2000
90 days to decision

K002795 · Product code: **CBF** · Anesthesiology
Source: https://www.510kdatabase.net/k002795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Hyperbaric (CBF)
Date received	Sep 7, 2000
Decision date	Dec 6, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hypertec, Inc.**
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	2 submissions · 2 cleared · 2000-2000