FDA 510(k) Premarket Notification

K792679 HISTOPLASMA CAPSULATUM, ANTISERUM

CLEARED

Jan 17, 1980
21 days to decision

K792679 · Product code: **GMK** · Microbiology
Source: https://www.510kdatabase.net/k792679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Positive Control, Histoplasma Capsulatum (GMK)
Date received	Dec 27, 1979
Decision date	Jan 17, 1980
Days to decision	21 days
Third-party review	No

APPLICANT

Company	**Meridian Diagnostics, Inc.**
Location	Walker, MI, US
510(k) history	92 submissions · 92 cleared · 1980-1999