FDA 510(k) Premarket Notification

K792694 NEGATIVE CONTROL SERUM

CLEARED

Jan 24, 1980
28 days to decision

K792694 · Product code: **GMK** · Microbiology
Source: https://www.510kdatabase.net/k792694/

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 24, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

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