FDA 510(k) Premarket Notification

K801791 FERTILITY AWARENESS METHOD KIT

CLEARED

Oct 31, 1980
94 days to decision

K801791 · Product code: **FLK** · General Hospital
Source: https://www.510kdatabase.net/k801791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thermometer, Clinical Mercury (FLK)
Date received	Jul 29, 1980
Decision date	Oct 31, 1980
Days to decision	94 days
Third-party review	No

APPLICANT

Company	**Telesis Corp.**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1980-1980