FDA 510(k) Premarket Notification

K802454 GESTE FOLLOW KIT DETERM. OF HPL

CLEARED

Nov 12, 1980
35 days to decision

K802454 · Product code: **JMF** · Immunology
Source: https://www.510kdatabase.net/k802454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Human Placental Lactogen (JMF)
Date received	Oct 8, 1980
Decision date	Nov 12, 1980
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Syn-Kit, Inc.**
Location	Walker, MI, US
510(k) history	34 submissions · 34 cleared · 1980-1986