FDA 510(k) Premarket Notification

K811815 UROPAPER EIKEG

CLEARED

Dec 10, 1981
167 days to decision

K811815 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k811815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Jun 26, 1981
Decision date	Dec 10, 1981
Days to decision	167 days
Third-party review	No

APPLICANT

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