FDA 510(k) Premarket Notification

K842571 IMMPULSE DIGOXIN ASSAY REAGENTS

CLEARED

Aug 16, 1984
44 days to decision

K842571 · Product code: **KXT** · Toxicology
Source: https://www.510kdatabase.net/k842571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Jul 3, 1984
Decision date	Aug 16, 1984
Days to decision	44 days
Third-party review	No

APPLICANT

Company	**Aktis Corp.**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1984-1984