FDA 510(k) Premarket Notification

K883279 PHASE II FSH KIT

CLEARED

Sep 9, 1988
37 days to decision

K883279 · Product code: **CGJ** · Chemistry
Source: https://www.510kdatabase.net/k883279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Aug 3, 1988
Decision date	Sep 9, 1988
Days to decision	37 days
Third-party review	No

APPLICANT

Company	**Vitek Systems, Inc.**
Location	Mchenry, IL, US
Contact	KEN HOFFMAN
510(k) history	39 submissions · 39 cleared · 1978-1993