FDA 510(k) Premarket Notification

K943996 DUPONT ACA PLUS LUTEINIZING HORMONE (LH) METHOD

CLEARED

Oct 20, 1994
65 days to decision

K943996 · Product code: **CEP** · Toxicology
Source: https://www.510kdatabase.net/k943996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Aug 16, 1994
Decision date	Oct 20, 1994
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dupont Medical Products**
Location	Wilmington, DE, US
Contact	REBRCCA AYASH
510(k) history	28 submissions · 28 cleared · 1991-1995