

K863929 TERUMO SENSIBEAD(TM) EIA HLH KITNov 13, 1986
36 days to decisionK863929 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k863929/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Oct 8, 1986
Decision date	Nov 13, 1986
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	HARALD JACOBY
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863929/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026