

**K894279 LUTEINIZING HORMONE MAB SOLID PHASE
COMPONENT SYST**Aug 15, 1989
53 days to decisionK894279 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k894279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jun 23, 1989
Decision date	Aug 15, 1989
Days to decision	53 days
Third-party review	No

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	RUSSELL ARNSBERGER
510(k) history	632 submissions · 625 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894279/>; 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 21, 2026