

**K880758 SUCROSEP SPECIFIC IMMUNORADIOMETRIC ASSAY**Apr 18, 1988  
53 days to decisionK880758 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k880758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Feb 25, 1988
Decision date	Apr 18, 1988
Days to decision	53 days
Third-party review	No

**APPLICANT**

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Company	<b>Boots-Celltech Diagnostics, Inc.</b>
Location	Walker, MI, US
Contact	STEPHEN R ABBOTT
510(k) history	20 submissions · 20 cleared · 1984-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880758/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026