

**K000471 FUTURE DIAGNOSTICS B.V. STAT-INTRAOPERATIVE
INTACT PTH KIT**Apr 11, 2000
57 days to decisionK000471 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k000471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Feb 14, 2000
Decision date	Apr 11, 2000
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Future Diagnostics B.V.
Location	San Diego, CA, US
Contact	DAVE D SMITH
510(k) history	2 submissions · 2 cleared · 2000-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000471/>. 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 June 30, 2026