

K822053 ZETAPHASE-DIGJul 27, 1982
14 days to decisionK822053 · Product code: **DON** · Chemistry
Source: <https://www.510kdatabase.net/k822053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Solid Phase Sep. (DON)
Date received	Jul 13, 1982
Decision date	Jul 27, 1982
Days to decision	14 days
Third-party review	No

APPLICANT

Company	Biological & Diagnostic Products
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1982-1982

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k822053/> 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 July 5, 2026