

**K853048 APO-SCREEN TEST SET FOR HDL-APOLIPOPTIN
A-1**

Aug 28, 1985
40 days to decision

K853048 · Product code: **DER** · Immunology
Source: <https://www.510kdatabase.net/k853048/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER)
Date received	Jul 19, 1985
Decision date	Aug 28, 1985
Days to decision	40 days
Third-party review	No

APPLICANT

Company	Photec Diagnostics, Inc.
Location	Little Falls, NJ, US
Contact	JAMES F MONGIARDO
510(k) history	12 submissions · 12 cleared · 1985-1990

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Device record: <https://www.510kdatabase.net/k853048/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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