FDA 510(k) Premarket Notification

K964296 N-ASSAY TIA APO B TEST KIT

CLEARED

Aug 1, 1997
276 days to decision

K964296 · Product code: **DER** · Immunology
Source: https://www.510kdatabase.net/k964296/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER)
Date received	Oct 29, 1996
Decision date	Aug 1, 1997
Days to decision	276 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Crestat Diagnostics, Inc.**
Location	Portland, OR, US
510(k) history	29 submissions · 29 cleared · 1990-1998