FDA 510(k) Premarket Notification

K093485 VESISCAN

CLEARED

Mar 16, 2010
127 days to decision

K093485 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k093485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 9, 2009
Decision date	Mar 16, 2010
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Life-Tech, Inc.**
Location	Stafford, TX, US
Contact	JEFF KASOFF
510(k) history	14 submissions · 14 cleared · 2005-2012