FDA 510(k) Premarket Notification

K093371 MODEL DGH 6000 SCANMATE A

CLEARED

Apr 5, 2010
158 days to decision

K093371 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k093371/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 29, 2009
Decision date	Apr 5, 2010
Days to decision	158 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Dgh Technology, Inc.**
Location	Frazer, PA, US
Contact	M. LUTHER DETWEILER
510(k) history	7 submissions · 7 cleared · 1987-2017