FDA 510(k) Premarket Notification

K083745 THE IC-PRO SYSTEM, MODEL VERSION 3.2

CLEARED

Feb 17, 2009
63 days to decision

K083745 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k083745/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Dec 16, 2008
Decision date	Feb 17, 2009
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Paieon, Inc.**
Location	New York, NY, US
Contact	SHAHAR MANDELBOIM
510(k) history	8 submissions · 8 cleared · 2004-2012