FDA 510(k) Premarket Notification

CLEARED

K180989 PEDRA-17F Digital Flat Panel X-ray Detector

Jun 13, 2018
58 days to decision

K180989 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k180989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Apr 16, 2018
Decision date	Jun 13, 2018
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Radisen, Inc.**
Location	Seoul, KR
Contact	John Lim
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k180989/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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