

**K013897 SOLID STATE X-RAY IMAGING DEVICES, MODEL IRIS
20 AND IRIS 41 WITH IRIS VIEW**

May 21, 2002
179 days to decision

K013897 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k013897/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 23, 2001
Decision date	May 21, 2002
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Scan S.A
Location	Stamford, CT, US
Contact	RICHARD M SANO
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013897/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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