

K102533 ROTATING GAMMA SYSTEM INFINI (INFINI)Mar 22, 2011
200 days to decisionK102533 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k102533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Sep 3, 2010
Decision date	Mar 22, 2011
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Masep Medical Science & Tech.Development (Shenzhen
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	1 submissions · 1 cleared · 2011-2011

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