

K162954 OARtrac System with Patient Specific Reusable Universal PSD Sensors

Jun 1, 2017
220 days to decision

K162954 · Product code: **NZT** · Radiology
Source: <https://www.510kdatabase.net/k162954/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dosimeter, Ionizing Radiation, Implanted (NZT)
Date received	Oct 24, 2016
Decision date	Jun 1, 2017
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiadyne, LLC
Location	Houston, TX, US
Contact	JOHN K. ISHAM
510(k) history	2 submissions · 2 cleared · 2015-2017

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Device record: <https://www.510kdatabase.net/k162954/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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