FDA 510(k) Premarket Notification

CLEARED

K182572 InstaRISPACS / InstaZFP / InstaMobi v5.0

Apr 12, 2019
206 days to decision

K182572 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k182572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 18, 2018
Decision date	Apr 12, 2019
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meddiff Technologies Pvt. , Ltd.**
Location	Denton, TX, US
Contact	Mr. Sanjeev
510(k) history	2 submissions · 2 cleared · 2012-2019

REGULATORY CONSULTANT

Consulting firm	**O Tech, Inc.**
Contact	Carl Alletto

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov