

K181498 X-ray Imaging System for the McLaren Proton Treatment System

Dec 10, 2018
186 days to decision

K181498 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k181498/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jun 7, 2018
Decision date	Dec 10, 2018
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ehmetdx, LLC
Location	Plymouth, MI, US
Contact	Daniel Schoettlin
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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