FDA 510(k) Premarket Notification

K200916 Patient Administration Set

CLEARED

Sep 1, 2020
148 days to decision

K200916 · Product code: **IYT** · Radiology
Source: https://www.510kdatabase.net/k200916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Rebreathing, Radionuclide (IYT)
Date received	Apr 6, 2020
Decision date	Sep 1, 2020
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cyclomedica Australia Pty, Ltd.**
Location	Kingsgrove, AU
Contact	Niamh Mc Aree
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Certus International, Inc.**
Contact	Karen Wolfe-Kerker

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