FDA 510(k) Premarket Notification

K192083 Okami Medical LOBO Vascular Occlusion System

CLEARED

Oct 30, 2019
89 days to decision

K192083 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k192083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Aug 2, 2019
Decision date	Oct 30, 2019
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Okami Medical**
Location	Aliso Viejo, CA, US
Contact	Rebecca K Pine
510(k) history	3 submissions · 3 cleared · 2019-2022