FDA 510(k) Premarket Notification

K191324 CivaDerm

CLEARED

Sep 20, 2019
127 days to decision

K191324 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k191324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	May 16, 2019
Decision date	Sep 20, 2019
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Civatech Oncology, Inc.**
Location	Mebane, NC, US
Contact	Suzanne Babcock
510(k) history	3 submissions · 3 cleared · 2008-2019

REGULATORY CONSULTANT

Consulting firm	**TAMM Net, Inc.**
Contact	Blix Winston

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