

K191324 CivaDermSep 20, 2019
127 days to decisionK191324 · 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

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