

K190155 FibermarX Radiopaque Tissue MarkerFeb 27, 2019
28 days to decisionK190155 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k190155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 30, 2019
Decision date	Feb 27, 2019
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Viscus Biologics, LLC
Location	Stillwater, MN, US
Contact	Justin Baker
510(k) history	3 submissions · 3 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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