

**K121964 MARKIT TISSUE MARKER-1ML MARKIT TISSUE
MARKER-3ML MARKIT TISSUE MARKER-10ML**Jan 23, 2013
202 days to decisionK121964 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k121964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jul 5, 2012
Decision date	Jan 23, 2013
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Augmenix, Inc.
Location	Waltham, MA, US
Contact	Eric Ankerud
510(k) history	5 submissions · 4 cleared · 2013-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121964/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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