

**K012955 COAPTITE TISSUE MARKER AND COAPTITE FN
TISSUE MARKER**

Oct 22, 2001
48 days to decision

K012955 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k012955/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Sep 4, 2001
Decision date	Oct 22, 2001
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioform, Inc.
Location	Franksville, WI, US
Contact	VICTOR M BOWERS
510(k) history	4 submissions · 4 cleared · 2001-2003

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k012955/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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