

**K111692 TUMARK FLEX FOR MAMMOTOME, TUMARK FLEX
FOR ATEC**Nov 8, 2011
145 days to decisionK111692 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k111692/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jun 16, 2011
Decision date	Nov 8, 2011
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Somatex Medical Technologies GmbH
Location	Cambridge, MA, US
Contact	HARALD JUNG
510(k) history	7 submissions · 7 cleared · 2008-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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