

**K021397 EMBOSPHERE MICROSPHERES AND EMOGOLD
MICROSPHERES FOR USE IN UTERINE FIBROID
EMBOLIZATION**Nov 22, 2002
204 days to decisionK021397 · Product code: **NAJ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k021397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	May 2, 2002
Decision date	Nov 22, 2002
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosphere Medical, Inc.
Location	Rockland, MA, US
Contact	SHIELA HEMEON-HEYER
510(k) history	6 submissions · 6 cleared · 2001-2012

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