Class I Medical Device Recall: Vycor Medical, Inc., Vycor Viewsite Brain Access System (VBAS)

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: August 21, 2012

Product: Vycor Viewsite Brain Access System (VBAS), Model #TC171105, Lot #VM83450

This product was manufactured on May 29, 2011 and distributed from June 8, 2012 through July 9, 2012.

Use: The Vycor Medical Viewsite Brain Access System serves as a self-retaining retractor system for brain tissue and provides access to allow the surgeon to see the surgical site during brain and spinal procedures.

Recalling Firm:
Vycor Medical, Inc.
6401 Congress Ave, Suite 140
Boca Raton, Florida 33487-2841

Manufacturer:
Lacey Manufacturing Company
1146 Barnum Ave.
Bridgeport, Connecticut 06610-2705

Reason for Recall: Vycor Medical recalled its VBAS because an unidentified black fiber was found on the device. This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions can contact the company at 561-558-2020.

FDA District: Florida District Office

FDA Comments: Vycor Medical called their customers requesting that they place products of Model # TC171105, Lot # VM83450 into quarantine until further notice. Vycor Medical asked customers holding the affected lots to call the company immediately. Customers in immediate need of the product should advise the Vycor customer service team who can assist in providing an alternative product.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious

adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

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Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm