Kips Bay lands FDA approval to begin eSVS mesh study

Mass Device

The FDA awards conditional IDE approval to Kips Bay Medical, allowing the company to begin a clinical study of its eSVS mesh in coronary artery bypass graft surgery.

Kips Bay Medical [1] (NSDQ:KIPS [2]) won conditional FDA investigational device exemption approval for its eSVS mesh, allowing the company to begin a clinical study of the device in use during coronary artery bypass procedures.

The eSVS mesh provides support to keep vein grafts open during CABG procedures, and the FDA's blessing grants Kips Bay approval to include 4 U.S. study sites in its ongoing eMESH I clinical feasibility trial.

The eMESH studies began in Switzerland in August 2012 [3] in hopes of reversing a previous FDA rejection of an eSVS IDE application.

Links:
[1] http://www.massdevice.com/companyorganization/kips-bay-medical-inc
[2] http://www.google.com/finance?q=kips
[3] http://www.massdevice.com/news/study-kips-bay-begins-us-feasibility-trial-vascular-mesh