DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 4, 2014

Cousin Biotech
Mr. Frank Pelletier
Regulatory Affairs Director
8 Rue de L'Abbé Bonpain
F 59117 Wervicq-Sud, France

Re: K133889
Trade/Device Name: Premium
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 31, 2014
Received: August 4, 2014

Dear Mr. Pelletier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: PREMIUM

Indications for Use:

PREMIUM are surgical meshes that are indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Abbreviated 510k

PREMIUM

510(k) SUMMARY

As required by section 807.92(c)

Submitter	COUSIN BIOTECH 8 rue de l'Abbé Bonpain F59117 WERVICQ SUD FRANCE
Contacts	Franck PELLETIER Regulatory Affairs Director f.pelletier@cousin-biotech.com
Preparation date	18 December 2013
Trade Name	PREMIUM
Common Name	POLYMERIC SURGICAL MESH
Classification Name	MESH SURGICAL POLYMERIC
Regulation number	878.3300
Product code	FTL
Class	II
Legally marketed predicate devices	PREMIUM is compared to PROLENE SOFT (K001122) manufactured by ETHICON, INC.
Description	PREMIUM medical devices are surgical meshes with light polypropylene. They are non resorbable parietal reinforcement implants.
Intended Use	PREMIUM devices are surgical meshes that are indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
Performance data	PREMIUM conforms to the special control "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh". Testing include: Tensile strength, Stiffness, Suture pullout strength, Burst strength and Tear resistance. No clinical data has been presented.

Abbreviated 510k

PREMIUM

Substantial equivalence	PREMIUM is substantially equivalent to its predicated devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrates that PREMIUM is as safe, as effective, and performs as safety and effectively as its predicate devices.