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

August 6, 2014

Synthasome Incorporated
Anthony Ratcliffe, Ph.D.
President and Chief Executive Officer
3030 Bunker Hill Street, #308
San Diego, California 92109

Re: K141394
Trade/Device Name: X-Repair
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, OWW
Dated: July 9, 2014
Received: July 10, 2014

Dear Dr. Ratcliffe:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141394

Device Name
X-Repair

Indications for Use *(Describe)*
X-Repair is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.
X-Repair is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.
X-Repair is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S

510(k) SUMMARY

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number:	3008008164
Address of Manufacturer:	Synthasome, Inc. 3030 Bunker Hill Street, #308 San Diego, CA 92109 Phone: (858) 490-9400 FAX: (858) 490-9404
Contact Person:	Anthony Ratcliffe, PhD President and CEO
Date Prepared:	May 15, 2014
Trade or Proprietary Name:	X-Repair
Common or Usual Name:	Surgical mesh
Classification Name:	21 CFR 878.3300, class II, FTL: Mesh, Surgical, Polymeric
Predicate Device Identification:	X-Repair (K083307)

Device Description:

The X-Repair is a bioabsorbable, rectangular, double-layered, flexible, woven surgical mesh manufactured from poly-l-lactic acid (PLLA) fiber. It has locked top and bottom edges and welded ends. It is provided sterile, intended for single use, and labeled non-pyrogenic.

Intended use and comparison to predicate devices:

X-Repair is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

X-Repair is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

X-Repair is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair.

"Indications for Use" are identical to the predicate X-Repair (K083307).

"Directions for Use" are identical to the predicate X-Repair (K083307).

Product labels have been modified to reflect the additional sizes and additional part numbers.

Technological characteristics and comparison to predicate devices:

The technological characteristics are identical to the predicate X-Repair (K083307), namely :

- Have the same indications for use
- Use the same basic technology
- Have equivalent mechanical properties
- Incorporate the same basic woven fabric design
- Use the same PLLA fiber material
- Are packaged and sterilized using the same materials and processes

Minor changes to the predicate comprise additional widths for the device, starting at 4mm up to 40mm (the largest width of the predicate) and additional lengths for the device, starting at 20mm up to 160mm. In addition, the shelf life has been expanded to five (5) years.

Summary of performance data:

Bench testing was conducted to evaluate the tensile strength and suture pullout strength of the subject device. The results showed that the subject device has similar performance characteristics as the predicate device. In addition, the package integrity was tested to evaluate the maintenance of the sterile barrier and the maintenance of mechanical properties up to five years. The results of performance testing demonstrated that the functionality, integrity, and safety of the X-Repair are adequate for its intended use and do support a determination of substantial equivalence.