510(k) SUMMARY

MAR 2 7 2009

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

Establishment Registration Number:	To be determined.
Address of Manufacturer:	Synthasome, Inc. 3030 Bunker Hill Street, #308 San Diego, CA 92109
Contact Person:	Anthony Ratcliffe, PhD President and CEO
Date Prepared:	November 7, 2008
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:

- SportMesh™/Artelon® Tissue Reinforcement (K071887)
- Artimplant AB SportMesh™ (K052830)
- Vicryl Mesh (K810428)

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.

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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.

Compared with the predicate devices, the X-Repair has the same general intended use as the predicate devices (i.e., to support soft tissues where weakness exists). Further, the X-Repair and the SportMesh™/Artelon Tissue Reinforcement device are additionally indicated for the "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."

Technological characteristics and comparison to predicate devices:

The principal technological difference between the subject and predicate devices is the material used in the construction of the devices. The subject device is manufactured from poly-l-lactic acid, whereas the predicate devices are manufactured from either Artelon™, a proprietary biomaterial, or Vicryl. Similarly, however, PLLA, Artelon™, and Vicryl are all bioabsorbable materials. Minor differences also exist in the available device sizes and suture anchoring features. The differences in technological characteristics between the subject and predicate devices, however, do not raise new types of safety or effectiveness questions. Specifically, usual questions regarding biocompatibility, mechanical integrity, and device functionality exist, and accepted scientific methods exist for assessing the effect of the new device characteristics.

Summary of performance data:

The results of performance testing, including biocompatibility, mechanical, and animal 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthasome, Inc.
% Anthony Ratcliffe, Ph.D
3030 Bunker Hill Street, #308
San Diego, California

MAR 2 7 2009

Re: K083307
Trade/Device Name: Synthasome X-Repair
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 19, 2009
Received: February 23, 2009

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 Fed-ral 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083307

Indications for Use

510(k) Number (if known): _____ *(To be assigned by FDA)*

Device Name: Synthasome X-Repair

Indications for Use:

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.

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Prescription Use: **X**	AND/OR	Over-the-Counter Use: _____
(21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM 3/27/09

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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