August 3, 2023

S.B.M. SAS (Science & Bio Materials)
Anne Cospin-Latapie
Quality & Regulatory Affairs Manager
ZI du Monge
Lourdes, 65100
France

Re: K223122
Trade/Device Name: Menix® / Menix® Duo
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: April 24, 2023
Received: April 27, 2023

Dear Anne Cospin-Latapie:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Jesse Muir, Ph.D
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223122

Device Name
MENIX® / MENIX® DUO

Indications for Use *(Describe)*
The MENIX® / MENIX® DUO Meniscal Suture Systems are indicated for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures. The MENIX® / MENIX® DUO systems are indicated for use in meniscal repairs and allograft transplant procedures. The MENIX® / MENIX® DUO systems are intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.
The MENIX ® / MENIX® DUO devices are intended for single use only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5 – 510(K) SUMMARY

510(k) SUMMARY

1. SUBMITTER

S.B.M. SAS SCIENCE & BIO MATERIALS ZI du Monge F 65100 LOURDES – FRANCE Registration Number: 3004549189
Phone: +33 (0)5 62 42 21 01 Fax: +33 (0)5 62 42 21 00
Contact Person: Anne COSPIN-LATAPIE e-mail : anne.cospin@sbm-fr.com
Date prepared: 30 September 2022

2. DEVICE

Trade Name of Device	MENIX® / MENIX® DUO
Common or Usual Name	Meniscal Suture System
Classification Name	Suture, nonabsorbable, synthetic, polyethylene
Regulation number	21 CFR 878.5000
Regulatory Class	II
Product Code	GAT

3. PREDICATE DEVICES (legally marketed devices to which equivalence is claimed)

- FAST-FIX 360 Meniscal Repair System (K121861)

4. DEVICE DESCRIPTION

The devices included within this 510k are listed below:

Reference	**Nom / *Name***	**Cond./ *Pack.***
MEN0201901	MENIX® DUO Meniscal Suture System, 2 anchors	x1
MEN0201902	MENIX® Meniscal Suture System, 1 anchor	x1

The MENIX® / MENIX® DUO devices are intended to be used for all-inside meniscal repair:

- The **MENIX®** system consists of a single-use launcher which deploys a nonabsorbable implant composed of
  one anchor pre-tied with a suture.

- **MENIX® DUO** system consists of a single-use launcher which deploys a nonabsorbable implant composed of
  two anchors connected by a suture.

Each anchor is pre-mounted on a needle to allow its deployment through the meniscus by pressing on the associated button. A transparent sheath acts as a penetration depth limiter and as a protection for users. As the MENIX® meniscal suture system consists of only one anchor associated with a suture, this suture must be tied to another MENIX® / MENIX® DUO meniscal suture system. The devices are supplied sterile, individually packaged and ready to use

5. MATERIALS

Implant(s) Anchor: PEEK
Suture: UHMWPE, chrome-cobalt-aluminum dye Launcher
Needle: 316L steel
Transparent cannula: Polyamide PEBAX® Handle & button: Polycarbonate

6. INDICATION FOR USE

The MENIX® / MENIX® DUO Meniscal Suture Systems are indicated for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures. The MENIX® / MENIX® DUO systems are indicated for use in meniscal repairs and allograft transplant procedures. The MENIX® / MENIX® DUO systems are intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.
The MENIX ® / MENIX® DUO devices are intended for single use only.

7. PERFORMANCE DATA

The results of non-clinical testing, including biocompatibility, biological and mechanical performances, indicated that the device was functional within its intended use and equivalent to the predicate device.

The biocompatibility was evaluated according to the ISO 10993-1 (2018) through the risk analysis approach. Evaluation included assessment of existing data and chemical characterization. All acceptance criteria were met and MENIX ® / MENIX® DUO meniscal suture system were deemed biologically safe.

The mechanical performance data demonstrates that MENIX ® / MENIX® DUO meniscal suture system met performance specifications for traction strength and fatigue displacement traction strength through Dynamic then static tensile tests based on established acceptance criteria taken from the state of the art (Baraber’s studies) and in comparison to the predicate device FAST-FIX 360 Meniscal Repair System (K121861).

8. SUBSTANTIAL EQUIVALENCE

The MENIX® & MENIX® DUO Meniscal Suture Systems were demonstrated to be substantially equivalent in indications and design characteristics to the following predicate device previously cleared by the FDA.

- FAST-FIX 360 Meniscal Repair System (K121861)

There are minor differences between the MENIX® & MENIX® DUO Meniscal Suture Systems and the predicate device like the size of the PEEK anchor and the shape of the suture (one uses round suture and one uses flat). Those differences do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

In conclusion, the MENIX® & MENIX® DUO Meniscal Suture Systems are substantially equivalent to their predicate device FAST-FIX 360 Meniscal Repair System.