January 11, 2021

Biopsybell s.r.l.
% Maurizio Pantaleoni
Senior Consultant
Maytal Doo
Kneza Milosa, 79
Belgrade, Serbia 11000
Serbia

Re: K203397
Trade/Device Name: BONE MARROW MSC ASPIRATION KIT
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: November 6, 2020
Received: November 18, 2020

Dear Maurizio Pantaleoni:

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 and Part 809); 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K203397

Device Name
BONE MARROW MSC ASPIRATION KIT

Indications for Use *(Describe)*
The BONE MARROW MSC ASPIRATION KIT is intended for use for aspiration / explant of bone marrow through a piston syringe.

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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1. General Information

Submitter :

Biopsybell srl is located at:
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Summary Preparation Date: January 06th, 2021

2. Name & Classification

Device Name:	BONE MARROW MSC ASPIRATION KIT
Common Name:	Bone Marrow Biopsy Needle
Regulation Name:	Gastroenterology-urology biopsy instrument
Regulation Number:	876.1075
Product Code:	KNW
CLASS:	II

3. Predicate Devices

The BONE MARROW MSC ASPIRATION KIT is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number
RANFAC	Marrow Cellution Bone Marrow Aspiration Needle	K150563
BIOPSYBELL	Manual-bone-marrow-biopsy-needles, Semi-automatic-biopsy-needles, Automatic-biopsy-needles	K130616

4. Indications for Use

The BONE MARROW MSC ASPIRATION KIT is intended for use for aspiration / explant of bone marrow through a piston syringe.

5. Device Description

The BONE MARROW MSC ASPIRATION KIT is a single use disposable needle intended for the aspiration / explant of bone marrow.

The structure of BONE MARROW MSC ASPIRATION KIT device includes a cannula with a stylet inside, with a threaded insert and a rotating spacer that allow the precise retraction of the cannula to a determined length.

Once the cannula has been inserted and positioned, the stylet can be removed and a syringe is connected to execute the aspiration.
By manually rotating the rotating spacer, the cannula retracts, raising inside the bone marrow, in order to be able to perform aspiration / explant from fresh sites at different heights.

6. Comparison with the predicate devices

	Subject device	**Predicate device (K150563)**	**Reference device (K130616) Orion Explant**	**Reference device (K130616) OSTEOBELL T**
Device	BONE MARROW MSC ASPIRATION KIT	Marrow Cellution Bone Marrow Aspiration Needle	ORION EXPLANT – Needle for bone-marrow explant	OSTEOBELL T – Needle for bone-marrow biopsy
510(K) number	-	**(**K150563**)**	**(**K130616**)**	**(**K130616**)**
Applicant	BIOSPYBELL S.R.L.	RANFAC	BIOPSYBELL S.R.L.	BIOPSYBELL S.R.L.
Classification				
Reg. Number	876.1075	876.1075	876.1075	876.1075
Product Code	KNW	KNW	KNW	KNW
Regulatory Class	II	II	II	II
Intended use				
Intended use	The BONE MARROW MSC ASPIRATION KIT is intended for use for aspiration / explant of bone marrow through a piston syringe.	The Marrow Cellution Bone Marrow Aspiration Needle is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.	needle for bone-marrow explant	needle for bone-marrow biopsy

	Subject device	Predicate device (K150563)	Reference device (K130616) Orion Explant	Reference device (K130616) OSTEOBELL T
Mechanism of Action / Mode of Action	The mechanism of action is bone marrow aspiration / explant. The needle is placed manually, then with a single puncture, is possible to collect bone marrow samples at different heights through the rotation of the rotating spacer.	The mechanism of action is bone marrow aspiration / explant. The needle is placed manually, then with a single puncture, is possible to collect bone marrow samples at different heights through the rotation of the ring nut.	The mechanism of action is bone marrow aspiration / explant. The needle is placed manually, then with a single puncture, is possible to collect bone marrow samples at different heights through the rotation of the ring nut.	The mechanism of action is bone marrow biopsy. The needle is placed manually, then with a single puncture, is possible to collect bone marrow samples.
Design Features				
Single Use Device	YES	YES	YES	YES
Dimensions of cannula (length / gauge)	10 cm / 11 gauge 10 cm / 13 gauge	9 cm / 11 gauge 11,4 cm / 11 gauge	11 – 13 - 14 – 15 - gauge Every gauge diameter is available in the following dimensions: 7, 9, 11, 13 cm	7 – 8 – 9 – 11 – 13 gauge Every gauge diameter is available in the following dimensions: 10, 15 cm
Materials				
Cannula	AISI 304 stainless steel	Stainless steel	AISI 304 stainless steel	AISI 304 stainless steel
Syringe	Polycarbonate / ABS / Silicone	N/A	N/A	N/A
Biocompatibility				
Standard	Compliant to ISO 10993-1:	Compliant to ISO 10993-1:	Cytotoxicity Intracutaneous reactivity	Cytotoxicity Intracutaneous reactivity
Sterilization				
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

7. Performance Data

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility; the following biocompatibility tests have been performed:
  - *Cytotoxicity*
  - *Sensitization*
  - *Irritation or intracutaneous reactivity*
  - *Material mediated pyrogenicity*
  - *Acute systemic toxicity*
- Verification of Washing Process
- Packaging shelf life accelerated aging tests
- Performance/Functionality/Safety; the following tests have been performed:
  - *Needle retraction efficacy*
  - *Excursion of the Needle threaded insert*
  - *Maximum useful length of the needle cannula*
  - *Needle aspiration surface*
  - *Needle handle Grip during bone insertion procedures*
  - *Needle perforation capacity in the bone*
  - *Adequacy of the Needle Luer-Lock Connection*

  - *Quantity of bone marrow sample collected by the needle*
  - *Integrity of the aspiration syringe*
- EO Sterilization Validation

Results of the evaluations demonstrate that the subject device met the safety and performance requirements as per its indication for use.

8. Clinical data

N/A

9. Conclusions

In light of evidences summarized above and based on classification, intended use, technological characteristics and performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.