March 26, 2018

Biopsybell s.r.l.
% Mr. Maurizio Pantaleoni
CEO
Isemed s.r.l
Via Togliatti 19/X,
Imola (BO) 40026, ITALY

Re: K180315
Trade/Device Name: DISKOM
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 1, 2018
Received: February 5, 2018

Dear Mr. 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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180315

Device Name
DISKOM

Indications for Use *(Describe)*
The DISKOM is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Summary of the K180315 DISKOM

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter :

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Summary Prepared Date: 2018-02-01

2. Names

Device Name:	DISKOM
Classification Name:	ARTHROSCOPE
Product Code:	HRX
Regulation number:	888.1100
CLASS:	II

3. Predicate Devices

The DISKOM is substantially equivalent to the following devices legally marketed in US:

Applicant	Device name	510(k) Number	Product code
GALLINI	Herniatome Percutaneous Discectomy Device	K141557	HRX
STRYKER	Stryker Decompressor Percutaneous Discectomy Probe	K032473	HRX

510(K) SUMMARY

4. Device Description

The DISKOM is a single use, active, EO sterilized device, that shall be used by specialized personnel during discectomy procedures.
The DISKOM is a disposable discectomy probe that passes through and works in conjunction with an introducer cannula to remove intervertebral disc nucleus pulposus.

DISKOM is composed by an INTRODUCER NEEDLE and a DISCECTOMY PROBE. The INTRODUCER NEEDLE is made of an aspiration cannula and an introducer stylet. The introducer needle is positioned on the disc (using CT / Fluoroscopic guide), then the stylet is removed and the cannula is used to position the discectomy probe.

The DISCECTOMY PROBE contains a battery source DC motor that causes the internal mechanism to act as a screw conveyor to remove and retrieve the excised debris of the spine through the outer cannula and into the transparent collection container.

The DISKOM is provided in two different models with two different cannula lengths (16cm and 8cm) and two different gauges cannulas (17G and 19G).

5. Indications for Use

The DISKOM is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.

6. Substantial equivalence discussion & Summary of Technological Characteristics

	Subject device	**Predicate device (K141557)**	**Predicate device (K032473)**
Product Name	DISKOM	Herniatome Percutaneous Discectomy Device	Stryker Decompressor Percutaneous Discectomy Probe
Manufacturer	BIOSPYBELL S.R.L.	GALLINI	STRYKER
510(K) No.	-	K141557	K032473
Regulation Name	Arthroscope	Arthroscope	Arthroscope
Regulation Number	888.1100	888.1100	888.1100
Classification	II	II	II
Product Code	HRX	HRX	HRX
Intended Use			
Indications for use	The Diskom is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.	The Herniatome Percutaneous Discectomy Device is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.	The Dekompressor percutaneous Discectomy Probe is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.

510(K) SUMMARY

Technical features			
Single Use Device	YES	YES	YES
Power	DC Motor – 9 Volt Battery	DC Motor – Battery	DC Motor – 9 Volt Battery
Maximum use time	10 minutes	Unknown	10 minutes
Configuration	Single use device with: - introducer needle composed by an external cannula and introducer stylet - Discectomy probe composed by a stylet with screw, a collection container and a grip with internal battery source DC motor - The stylet has 2 screws that enable the collection of disc material	Single use device with: - introducer needle composed by an external cannula and internal stylet - Discectomy probe composed by a stylet with screw, a collection container and internal battery source DC motor	Single use device with: - introducer needle composed by an external cannula and internal stylet - Discectomy probe composed by a stylet with screw, a collection container and internal battery source DC motor - the stylet has 2 screws in the device with length 3'' and 6'' and 3 screws in the one with length 9''
Dimensions of cannula (length / gauge)	16 cm / 17 gauge (thoracic / lumbar) 8 cm / 19 gauge (cervical)	15 cm / 17 gauge (lumbar) 9 cm / 17 gauge (cervical)	6" (15.24 cm) / 17 gauge (also available 13,15,19 gauge) – (thoracic / lumbar) 9" (22,86 cm) / 17 gauge (lumbar) 3" (7.62 cm) / 19 gauge (cervical)
Aspiration cannula hole position	Lateral hole	Lateral hole	Frontal hole
Materials			
Introducer Stylet	AISI 304 stainless steel	Stainless steel	Unknown
Cannula	AISI 304 stainless steel	Stainless steel	Unknown
Stylet with screw	Titanium	Stainless steel	Titanium
Biocompatibility			
Citotoxicity	Conforming to ISO 10993 testing (ISO 10993-5)	Conforming	Unknown
Sensitization	Conforming to ISO 10993 testing (ISO 10993-10)	Conforming	Unknown
Intracutaneous Reactivity	Conforming to ISO 10993 testing (ISO 10993-10)	Conforming	Unknown
Acute Systemic toxicity	Conforming to ISO 10993 testing (ISO 10993-11)	Conforming	Unknown
Bacterial endotoxins test (LAL test)	Conforming	Unknown	Unknown
Pyrogen test	Conforming	Unknown	Unknown
Electrical Safety / Electromagnetic Compatibility			
Electrical Safety / Electromagnetic Compatibility	Conforming to: IEC 60601-1 for electrical safety EN 60601-1-2 for Electromagnetic Compatibility	Conforming to: IEC 60601-1 electrical safety IEC 60601-1-2 for Electromagnetic Compatibility	Conforming to: IEC 60601-1 for electrical safety IEC 60601-1-2 for Electromagnetic Compatibility
Sterilization Shelf life			
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf life	3 years	3 years	3 years

Performance test for determination of the SE			
Performance tests	The following performance tests have been performed on the device, both on newly manufactured and aged products: • time of functioning (20 minutes) • engine rpm • quantity of tissue retrieved during the procedure • battery shelf life • maximum temperature at the level of the stylet with screw radiodetectability	The following performance tests have been performed on the device: • -volume flow rate study • -battery shelf life -radiodetectability	Unknown

7. Performance Data

7.1 Non clinical tests performed on the subject device

The following comparative tests have been performed for all BIOPSYBELL DISKOM codes:

1. *Time of functioning (20 minutes). Battery operation test for 20 minutes*
2. *Engine rpm.* Measurement of the number of rpm
3. *Quantity of tissue retrieved during the procedure.*
4. *Battery shelf life:* battery voltage measuring test during operation.
5. *Maximum Temperature at the level of the stylet with screw* measurement

The radiodetectability was another parameter tested. The radiopacity has been tested on subject device and on predicate device. T

Furthermore the following Biocompatibility tests were performed:

- Citotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic toxicity
- Bacterial endotoxins test (LAL test)
- Pyrogen test

Based on technological characteristics (intended use, dimensions and features) and performance data (comparative tests and biocompatibility tests) included in the present submission, the BIOPSYBELL DISKOM has been shown to be substantially equivalent to the listed predicate device.

7.2 Clinical tests performed on the subject device

No clinical test were performed on the subject device

510(K) SUMMARY

8 Conclusion

Based on technological characteristics (intended use, dimensions and features) and performance data (comparative tests and biocompatibility tests) and comparison discussion included in the present submission, the BIOPSYBELL DISKOM has been shown to be substantially equivalent to the listed predicate devices.