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

January 19, 2017

Biotekne S.r.l.
℅ Enrico Bisson
President
Studio di Ingegneria Enrico Bisson
Via Marzia 9
Abano Terme, Padova 35031
ITALY

Re: K161255
Trade/Device Name: meso-relle (AAL34, AAL36, AM30G)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 21, 2016
Received: December 22, 2016

Dear Enrico Bisson:

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" (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.

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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K161255

Device Name
meso-relle AAL34, AAL36, AM30G

Indications for Use *(Describe)*
The meso-relle needles are intended to inject fluids intradermally.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 05
510(k) Summary

510 (k) Summary

K161255

APPLICANT

Company Name:	Biotekne S.r.l.
Company Address:	Via della Bastia, 9
	40033 Casalecchio di Reno (BO) - ITALY
Company Phone:	+39 051565211
Company Fax:	+39 0516182524
Company e-mail	info@biotekne.it

CONTACT PERSON:	Enrico Bisson - Studio ingegneria Enrico Bisson
	Via Marzia n. 9
	Abano Terme (PD) - ITALY
Contact Phone:	+39 0498630080
Contact Fax	+39 0498630080
Contact E-mail	enrico.bisson@gmail.com

Date Summary Prepared: January 17, 2017

DEVICE IDENTIFICATION

A.	Trade name:	meso-relle AAL34, AAL36, AM30G
B.	Generic/ Common Name:	Hypodermic Needle
C.	Classification name:	Hypodermic single lumen needle, 21 CFR 880.5570, Class II
D.	Product Code:	FMI

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

K110606, MV Intradermic Needles, MV S.R.L.

Reference Predicate Device: K051783, Artsana Hypodermic Needles, ARTSANA SPA.

INDICATIONS FOR USE

The meso-relle needles are intended to inject fluids intradermally.

DEVICE DESCRIPTION

The meso-relle® needles are single lumen needle intended to inject fluids intradermally.

The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe.

Needles have different length, which make them suitable to inject fluids intradermally. The meso-relle are not intended for injection in the bloodstream. The devices do not contact the central nervous system. The meso-relle® needles are suitable for administration of fluids intradermally.

Each needle is provided with a protective cap (cover). The cover is rigid and not colored. The dimensions are suitable to accommodate the corresponding needle and vary according to the dimensions of the needle.

The meso-relle® needles are disposable single use devices, sold sterilized by ethylene oxide.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The meso-relle Needles are same or similar in materials, design and intended use to the predicate devices. Both the subject and the predicate devices are intended to inject fluids intradermally; they have the same indications for use. Each of the technical attributes of the meso-relle Needles are present in the predicate devices. The materials, tip configuration and other fundamental design characteristics are all the same. Comparison elements are as follows:

ATTRIBUTE / CHARACTERISTICS	meso-relle NEEDLES (Submitted Product)	MV Intradermic Needles (Legally Marketed Predicate Device)	Artsana Hypodermic Needles (Reference Predicate Device)	Comparison
'K" numbers	K161255	K110606	K051783	
CFR Section	880.5570	880.5570	880.5570	same
Pro-code	FMI	FMI	FMI	same
Classification name	Hypodermic single lumen needle	Hypodermic single lumen needle	Hypodermic single lumen needle	same
Intended / Indications For Use	The meso-relle needles are intended to inject fluids intradermally.	The MV intradermic needles are intended to inject fluids intradermally.	Artsana disposable sterile hypodermic needles are intended for use to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	same as the primary predicate
Cannula material	AISI 304 Stainless Steel	AISI 304 Stainless Steel	AISI 304 Stainless Steel	same
Hub material	Polypropylene (Polypropylene MG03MA)	Polypropylene (Polypropylene MG03MA)	Polypropylene	same
Hub color	Yellow CAS No. 22094-93-5, Dispersant (CAS No.557-04-0) internal material code: SCP-19906 color coded ISO 6009	Yellow CAS No. 22094-93-5, Dispersant (CAS No.557-04-0) internal material code: SCP-19906 color coded ISO 6009	Not available	same as the primary predicate
Cover	rigid cover, polypropylene or propylene\ethylene copolymer	rigid cover, polyethylene	rigid cover, non toxic propylene	same or similar
Adhesive	epoxy type adhesive	epoxy type adhesive	epoxy type adhesive	same
Lubricant	medical grade silicone oil	medical grade silicone oil	medical grade silicone oil	same

ATTRIBUTE / CHARACTERISTICS	meso-relle NEEDLES (Submitted Product)	MV Intradermic Needles (Legally Marketed Predicate Device)	Artsana Hypodermic Needles (Reference Predicate Device)	Comparison
'K" numbers	K161255	K110606	K051783	
Needle diameter (gauge)	30G	22G, 25G, 26G, 27G, 30G / pilot needle: 21G, 23G, 26G, 27G	27G, 30G	The needle diameter of the subject device is included within the configuration of the predicate devices
Needle length (mm)	4, 6, 12	25, 27,35, 37, 40, 50, 57, 70 / pilot needle: 13, 25	4, 6, 13	The differences in the needle length between the subject and the primary predicate device do not raise new questions of safety or effectiveness for the subject device. Shorter length needles are more appropriate for intradermal use.
Tip configuration	triple sharpened, non-coring	Injection needle: closed blunt tip, lateral opening Pilot needle: triple sharpened, non-coring	triple sharpened, non-coring	same as the MV pilot needle and as the reference predicate device
Connection to syringe or injection device	Luer taper	Luer taper	Luer taper	same
Sterilization	Ethylene Oxide (EO) Per ISO 11135-1:2007	Ethylene Oxide (EO) Per ISO 11135-1:2007	Not available	same as the primary predicate
SAL Level	SAL 10^{-6}	SAL 10^{-6}	Not available	same as the primary predicate
Biocompatibility	ISO 10993-1	ISO 10993-1	Not available	same as the primary predicate

ATTRIBUTE / CHARACTERISTICS	meso-relle NEEDLES (Submitted Product)	MV Intradermic Needles (Legally Marketed Predicate Device)	Artsana Hypodermic Needles (Reference Predicate Device)	Comparison
'K" numbers	K161255	K110606	K051783	
Functional testing	ISO 7864:2016 ISO 9626:2016 ISO 594-1:1986	ISO 7864:1993 ISO 9626:1991 ISO 594-1:1986	Not available	same as the primary predicate

The shorter length of the subject device do not raise new issues of safety or effectiveness; shorter lengths are even more suitable for intradermal use as they are less invasive. This difference does not affect the substantial equivalence of the subject device.
The test results and comparison results show that the subject device is substantial equivalent to the predicate in performance.

NON-CLINICAL PERFORMANCE DATA

All materials used for the meso-relle needles have a long history of safe use for the same or equivalent intended use. Biocompatibility has been tested according to the requirements of ISO 10993-1. In consideration of the International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, following biocompatibility tests were performed on the final finished device to evaluate: Cytotoxicity, Sensitization, Intracutaneous reactivity, Systemic toxicity and Haemolysis.

The sterility of the meso-relle Needles is assured by using a validated sterilization method which complies with the requirements of the Recognized Consensus Standard: AAMI / ANSI / ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
Ethylene oxide (EtO) and Ethylene Chlorohydrin (ECH) residuals were tested according to UNI EN ISO 10993-7: 2008 - Method K.4.3.+ HRGC/MS Detection for EtO and Method K.4.8+ HRGC/MS Detection for ECH and met the acceptance criteria.

Meso-relle Needles were tested according to ISO 7864:2016 “Requirements and test methods Sterile hypodermic needles for single use”, ISO 9626:2016 “Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods” and ISO 594-1:1986 “Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements” in order to demonstrate that the proposed device is substantial equivalent to the predicate in safety and performance.

CONCLUSION:

The subject and the predicate devices have the same indications for use and they have same technological characteristics. The test results and comparison results show that the proposed device is substantial equivalent to the predicate in performance.
Based on the intended use, technological characteristics and performance testing, the proposed product meso-relle Needles is considered to be substantially equivalent to the predicate device.