January 20, 2023

Pikdare S.p.A
Roberta Zanoni
Official Correspondent
Via Saldarini Catelli 10
Casnate con Bernate, COMO 22070
Italy

Re: K203792
Trade/Device Name: Insupen Pen needle, Insupen ORIGINAL Pen Needle, Insupen ADVANCED pen needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 19, 2022
Received: December 22, 2022

Dear Roberta Zanoni:

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,

Alan M. Stevens -S3

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203792

Device Name
Insupen Pen Needle
Insupen ORIGINAL pen needle
Insupen ADVANCED pen needle

Indications for Use *(Describe)*
Sterile, single use needles intended for use with pen injector devices for the subcutaneous injection of drugs

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.

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510(k) Summary

As required by the Medical Devices Act of 1990 and in accordance with 21 CFR §807.92(a).

Summary [807.92 (a)(1,2)]
Date Prepared: January 20, 2023
Submitted By:
Pikdare S.p.A
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Trade Name:
Insupen Pen Needle
Insupen ORIGINAL Pen needle
Insupen ADVANCED Pen Needle

Device models:
Insupen® Pen Needles 12 mm x 29G
Insupen®Pen Needles 8 mm x 30G
Insupen®Pen Needles 5 mm x 31G
Insupen®Pen Needles 6 mm x 31G
Insupen®Pen Needles 8 mm x 31G
Insupen®Pen Needles 4 mm x 32G
Insupen®Pen Needles 6 mm x 32G
Insupen®Pen Needles 8 mm x 32G
Insupen®Pen Needles 4 mm x 33G
Insupen®Pen Needles 3,5 mm x 34G
Insupen Original® Pen Needles 12 mm x 29G
Insupen Original ®Pen Needles 8 mm x 30G
Insupen Original ®Pen Needles 5 mm x 31G
Insupen Original ®Pen Needles 6 mm x 31G
Insupen Original ®Pen Needles 8 mm x 31G
Insupen Original ®Pen Needles 4 mm x 32G
Insupen Original ®Pen Needles 6 mm x 32G
Insupen Original ®Pen Needles 8 mm x 32G
Insupen Original®Pen Needles 4 mm x 33G
Insupen Advanced®Pen Needles 5 mm x 31G
Insupen Advanced®Pen Needles 4 mm x 32G
Insupen Advanced®Pen Needles 6 mm x 32G
Insupen Advanced®Pen Needles 4 mm x 33G
Insupen Advanced®Pen Needles 3,5 mm x 34G

Common Name: Pen Needle for drugs subcoutaneous injection
Regulation Number: 21 CFR § 880.5570
Product Code: FMI
Device Classification: II
Review Panel: 80 General Hospital
Predicate Device [807.92(a)(3)]

The legally marketed device to which substantial equivalence is claimed are:

	Manufacturer	Trade name	510K number
Reference device	Artsana SpA	Insupen pen needle	K051783
Primary Device	HTL-STREFA S.A.	DROPLET® PEN NEEDLE 34G	K192082

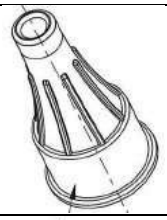
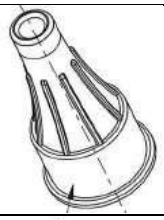
In 2019 Artsana SpA has moved the proprietary of its 510K (K051783) to Pikdare S.p.A

Description of Device: [807.92(a)(4)]
The Insupen Pen Needle/ Insupen ORIGINAL Pen needle/ Insupen ADVANCED Pen Needle are sterile, single use, single patient pen needles intended for use with pen injector devices for the subcutaneous injection of drugs. Pen needles are used by consumers, caregivers and healthcare professionals. The intended patients for this device is the population from newborn to elderly. The device can be used both in domestic and professional environment. It is considered MR unsafe.
The list of drugs tested and intended to be used with Pikdare's pen needle are Insulin, peptic hormone, peptic glucagon-like-1, and drug for the treatment of osteoporosis. All compatibility is checked following the requirements of ISO 11608-2:2012.

The pen needle assembly consists of a double-ended cannula that is assembled into an injection molded hub by gluing. The hub has internal threads which allow it to be screwed onto the pen injector device. This allows the cartridge end of the cannula to penetrate through the rubber septum of the cartridge. The patient end and the cartridge end of the cannula are lubricated using a silicone based lubricant for ease of injection and pen cartridge septum penetration. There is an inner needle shield assembled over the patient end of the cannula to protect the needle tip from damage and accidental needle sticks. Each pen needle is protected with a sealed medical paper which together with the primary container provide a sterility barrier. The pen needle is packaged in boxes and sterilized with ETO. It is intended for single patient and single use only. To use a pen needle, the user needs to remove the medical paper, screw the needle onto the pen injector device. Then the user removes both the outer cap and the inner protective cap to expose the needle and make an injection. After the injection, the needle is unscrewed from the pen injector device and disposed in an appropriate container respecting applicable regulations and laws.

Indications for Use: [807.92(a)(5)]
Sterile, single use needles intended for use with pen injector devices for the subcutaneous injection of drugs. Technological Characteristics: [807.92(a)(6)]-

Predicate Devices: [K051783; K192082]
A comparison of characteristics among Pikdare Pen Needles (New Device) and Predicate Device is shown in the table below, in which it is included the respective Indications for Use

	New Device	**Predicate Device**	**Conclusion**
Manufacturer	Pikdare SpA	HTL-STREFA S.A.	n/a
510(k) Number	Pending	K192082	n/a
Product Code	FMI	FMI	same
Proprietary name	Insupen Pen Needle Insupen Original Pen Needle Insupen Advanced Pen needle	Droplet 34G	
Primary Container			same
Needle Shield			same
Needle Tube and Hub			same
Indication for use	Pen Needle for drugs subcutaneous injection	Sterile, single use needles intended for use with pen injector devices for the subcutaneous injection of drugs	Same
Intended use	Pen Needle for drugs subcutaneous injection The patients target of this device is the population from newborn to elderly. The device can be used both in domestic and professional environment. MR Unsafe.	Pen Needle for drugs subcutaneous injection	Same
Principle of operation	Manual	Manual	same
Method of attachment to pen injector	Screw threads	Screw threads	same

	New Device	Predicate Device	Conclusion
Length	12mm 4mm 5mm 6mm, 8mm (tolerance ±1.25mm) 3.5mm (tolerance -0.4mm /+0.5mm)	3.5mm (tolerance -0.4mm /+0.5mm)	See discussion below
Gauge	29G, 30G, 31G, 32G, 33G, 34G	34G	See discussion below
Biocompatibility	Conforms to ISO 10993-1:2019	Conforms to ISO 10993-1:2019	same
Sterility	SAL = 10^{-6}	SAL = 10^{-6}	same
Sterilization method	ETO	ETO	same
Shelf Life	5 years	5 years	same
Unit Packaging	Blister composed by Primary container made of Polyethylene non-toxic for medical use (HDPE2) and seal made of medical grade paper (C/PAP22)	Blister composed by Primary container made of Polyethylene non-toxic for medical use (HDPE2) and seal made of medical grade paper (C/PAP22)	same
User Packaging	100 pcs Cardboard sales box (PAP 21)	Cardboard sales box (PAP 21)	same
Transport packaging	12 cardoboards sales boxes inside a corrugated carton container.(1200 pen needles in total) – (PAP 20)	12 cardoboards sales boxes inside a corrugated carton container.(1200 pen needles in total) (PAP 20	same
Materials			
Needle Tube	Medical Grade Stainless Steel AISI304L and AISI305	Medical Grade Stainless Steel AISI 304L	See Discussion
Hub	Polypropylene	Polypropylene	same
Needle Shield and Primary container	Polyethylene non-toxic for medical use	Polyethylene non-toxic for medical use	same
Lubricant	Medical grade silicone	Medical grade silicone	same
Glue (for hub and needle tube bonding)	UV glue – non-toxic	UV glue – non-toxic	same

The subject device and the Predicate devices are classified under 21 CFR 880.5570, which states: "A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin."
There are no differences in the main design, intended use (see details in the table above), principle of operation, method of attachment to pen injector devices, biocompatibility (see details in the table above), sterilization method, materials (see details in the table above), between the Pikdare pen needle device and the Predicate devices. Thus as detailed above the substantial equivalence is demonstrated

The Pikdare pen needle differs from the predicate device as shown in the table below:

GAUGES	LENGTH	PIKDARE PEN NEEDLE RANGE									PREDICATE DEVICE		
		INSUPEN			INSUPEN ORIGINAL			INSUPEN ADVANCED			K192082 (HTL-S.A.)		
		Availability	Stainless Steel	Wall type	Availability	Stainless Steel	Availability		Wall type	Wall type	Availability	Stainless Steel	Wall type
G29	12mm	X	AISI 304L	RW	X	AISI 304L	X	AISI 304 L	RW	-	-	-	-
G30	8mm	X	AISI 304L	RW	X	AISI 304L	-	-	-	-	-	-	-
G31	5mm	X	AISI 304L & AISI 305	ETW	X	AISI 304L & AISI 305	-	-	-	UTW	-	-	-
	6mm	X	AISI 304L & AISI 305	ETW	X	AISI 304L & AISI 305	X	AISI 304L	ETW (1)	-	-	-	-
	8mm	X	AISI 304L & AISI 305	ETW	X	AISI 304L & AISI 305	X	AISI 304L	ETW (1)	-	-	-	-
G32	4mm	X	AISI 304L & AISI 305	ETW	X	AISI 304L & AISI 305	-	-	-	UTW	-	-	-
	6mm	X	AISI 304L & AISI 305	TW	X	AISI 304L & AISI 305	-	-	-	ETW	-	-	-
	8mm	X	AISI 304L & AISI 305	TW	X	AISI 304L & AISI 305	-	-	-	-	-	-	-
G33	4mm	X	AISI 304L & AISI 305	TW	X	AISI 304L & AISI 305	-	-	-	ETW	-	-	-
G34	3,5mm	X	AISI 304L & AISI 305	TW	-	-	-	-	-	ETW	X	AISI 304L	TW

(1) Wall definition are declared based on the current revision of the standard.

In conclusion, analyzing the main differences between the subject device and the Predicate device, below these are the main consideration:

1. Pikdare Pen Needles are manufactured using both AISI304L and AISI 305 while the Predicate devices use AISI 304L only. AISI 305 is mentioned in the ISO 9626:2016 where it is stated that “tubing shall be made in the stainless steels listed in the ISO 15510” and our material is included in the standard, therefore there is no new impact on safety and performances.
2. Needle features and wall are confirmed to be compliant with ISO 9626 considering all the possible dimensions defining the wall. So there is no risk about the safety of the subject device
With reference to needle’s size G34, which is not covered by ISO 9626 requirements for stiffness, Pikdare SpA chooses to characterize the tube of this needle according to thestiffness test limits of G33 TW (as defined in ISO 9626:2016).
3. The Pikdare pen needle will be under OTC as well as the Predicate device K192082,

4. The Pikdare pen needle intended use is for injection of drugs in general as well as the Predicate device K192082. This feature does not introduce critical differences and new risks (migration and transfer tests has been carried out on needles with both intended uses).

The differences above indicated do not raise new questions of safety and/or functionality for the subject device. Considering that the Predicate device is covering G34 and 3,5mm only, while the Subject device is intended to cover the range of pen needles of G29 – G30 – G31 – G32 – G33 and G34 with lengths varying from 12mm to 3,5mm, we can declare that the products with extended gauges and lengths do not pose any new concerns in terms of safety and performance, since they have been submitted to tests according to the following recognized consensus standards:
-ISO 11608-2 Needle based injection system for medical use – Requirements and test methods – part 2: needles
-ISO 9626 Stainless steel needle tubing for the manufacture of Medical Devices – Requirements and Test Methods
-ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a Risk management Process
and the risk assessment carried out on them hasn't identified further risks not reduced to unacceptable level.

So, Pikdare pen needle product line has been demonstrated not having any impact on functional compatibility related to the combination of the pen needle with the pen injector devices including dose accuracy and limited differences in flow rates directly related to the differences of needle's internal diameter.

Based upon the above comparisons to the Predicate device, Pikdare Pen Needles are substantially equivalent to the Predicate device.

Non-Clinical Performance Data: [(807.92(b)(1)]
Pikdare pen needles successfully passed all the required non-clinical testing which included the following testing for compliance with the requirements of ISO 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles

Test Parameter	Requirement – ISO 11608-2:2012	Result Subject device	Result Predicate device	Conclusion
Materials	The needle shall be made of tubing materials specified in ISO 9626.	Requirement met	Requirement met	Both products use tubes specified in ISO 9626
Dimensions	The tubing features used in the needles shall meet the requirements of ISO 9626. For G34 needle the limits of stiffness has been chosen to comply with the same limits of G33 TW needle. The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2. The dimension shall comply with Table 1 of clause 4.2.2 of ISO 11608-2	Requirement met	Requirement met	Both products comply with the requirements of ISO 9626
Determination of flow rate through the needle	The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	Requirement met	Requirement met	Both products have the same flow rate
Bond between hub and needletube	The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Requirement met	Requirement met	Both products pass the breakage test

Needle points	Needle points shall appear sharp and free from featheredges, burrs and hocks when examinate under magnification x2,5. The needle point at the cartridge end is designed to minimize coring and fragmentation when penetrating the cartridge set.	Requirement met	Requirement met	Both products accomplish the needle requested features
Freedom from defects	The needle tube shall fulfill the requirements of ISO 7864,clause11.3.	Requirement met	Requirement met	Bothe products fulfill the ISO 7864
Lubrication	The needle tube should be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside	Requirement met	Requirement met	Both products respect the appropriate quantity of lubrication

	surface of the needle tube			
Dislocation of measuring point at patient end	Dislocation of the cannula point at the patient end shall be in accordance with Table 2 when tested in accordance with Clause 8 (of ISO 11608-2).	Requirement met	Requirement met	Both products are compliant with table 2.
Determination of functional compatibility with needle-based injection systems	Compatibility with any NIS (Needle-based Injection System) shall be claimed only after testing in accordance with Clause 11.	Requirement met	Requirement met	Both products are compatible to the same list of pen injector device
Ease of assembly and disassembly	Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.	Requirement met	Requirement met	Both products are in compliance with clause 11
Sterility	The needles in its unit packaging is subjected to a validatedsterilization process	Requirement met	Requirement met	Both products are ETO sterilized in the same sterilization place
Pre-conditioning of needles	The needles satisfy all the requirements of ISO 11608-2 after preconditioning according to clauses 6.1, 6.2 and 6.3 of the same standard.	Requirement met	Requirement met	Both products respect ISO 11608-2

Based on the comparison table on Non-Clinical Performance Data, we can declare that there is no difference between Subject device and the Predicate device.
Test were performed on both products, the total availability on sample of the Predicate device is due to the fact that the Predicate Device is manufactured in Pikdare factory in Italy (Pikdare is the contract manufacturer of Droplet G34 Pen Needle).

Biocompatibility testing:
Based on the test conduction according to ISO 10993-1 the medical device is categorized as follow:

- Nature of the body contact:
  - Category: externally communicating medical device
  - Contact: Blood path indirect
- Contact Duration: B – prolonged (>24 h to 30 d)

List of constituents (extract from the Biological Evaluation Plan)

The list of the device constituents provided by the sponsor is reported in Table 2.

Component	Material Type Type	Material Trade name	Supplier	Type of contact*
Primary Container	High Density Polyethylene Copolymer	ERACLENE ® MR 80 U	Versalis	None/Instant
		ERACLENE ® MS 80 U	Versalis	
		RIGIDEX HD5218EA	Ineos	
		RIGIDEX HD5226EA	Ineos	
Hub	Homopolymer Polypropylene	Eltex® MED 100-MG25	Ineos	None/Instant
		HEALTHCARE HPP25G	Repsol	
		PPM H250 or ACESO® PPM H250	Total	
Hub Master batch	Pigment for polymers Remafin Blue PE52080094 Pigment for polymers Remafin Yellow PE11078232 Pigment for polymers Remafin Grey PE71077043 Pigment for polymers Remafin Red PE31079060 Pigment for polymers Remafin Red PE31079091 Pigment for polymers Remafin Purple PE41076243 Pigment for polymers Remafin PP-All colours		Clariant	None/Instant
	Pigment for polymers Sicolen Green 90-0755 SN Pigment for polymers Sicolen Orange 28-5504		Basf	None/Instant
Cannulae	AISI 305 stainless steel		Bws	Direct
	AISI 305 stainless steel		Outokumpu	
	AISI 304 L stainless steel		Kobayashi	
UV Glue	UV3028		Loxeal	Direct
	AA3921		Loctite	
Lubricant	Medical silicon 360 12.500cps Medical silicone MDX4-4159 Q7 9180		Dow Corning	Direct
Shield	High Density Polyethylene Copolymer	ERACLENE ® MR 80 U	Versalis	None/Instant
		ERACLENE ® MS 80 U	Versalis	
		RIGIDEX HD5218EA	Ineos	
		RIGIDEX HD5226EA	Ineos	
Medical paper	Grid Coated Paper	0K08xxxx05x	Amcor	None/Instant
Box	Recycled cardboard		Autajon	None/Instant
Master	Carton B wave		Saica	None/Instant

Table 2: Constituents list.(*) instant contact is referred to the contact with the intact skin in order to use the device, therefore negligible

Biocompatibility Test Summary – no adverse biocompatibility effects were observed:

Test method	Compliance with	Result
Biological Risk AssessmentEvaluation	ISO 10993-1- Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	The following end-points have been identified and verified by testing.
Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	The test article showed no evidence of causing cell lysis or toxicity.
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
ISO Intracutaneous Study in Rabbits	ISO 10993-10 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	The test article met the requirements of the test.
ASTM Hemolysis Study	ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4 - Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood	Both the test article in direct contact with blood and the test article extract were non-hemolytic
ISO Two Week Toxicity Study in the Rat, Repeated Parenteral Administration of Two Extracts	ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	There were no microscopic changes considered to be a test article related response. Parenteral administration of the test article extract did not produce systemic toxicity in rats.
ISO Systemic Toxicity Study in Mice	ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article met the requirements of the study.
USP Rabbit Pyrogen Study, Material-mediated	ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	The total rise of rabbit temperatures during the 3 hours observation period was within acceptable USP limits. The test article was judged as non-pyrogenic
USP Pyrogen Study - Material Mediated	USP, General Chapter <151>, Pyrogen Test as recommended by ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	The test article was judged as nonpyrogenic.

Sterilization:

Product is EO sterilized in house by manufacturer. Sterilization process is validated using current standard ISO 11135-1:2014 + ISO 11135:2014/Amd 1:2018.

The sterilization cycle assures a SAL of 10^{-6}.

The maximum EO residual values after the degassing period, and before the product release, have been set at 1 mg for each device (ISO 10993-7 limit: 4 mg/day): these limits are set considering a maximum use of the devices equal to 4 times a day.
The maximum ECH residual values after the degassing period, and before the product release, have been set at 2,25 mg for each device (ISO 10993-7 limit: 9 mg/day): these limits are set considering a maximum use of the devices equal to 4 times a day.

The shelf life of the product, considering the integrity of the packaging and the sterility and physical properties, is 5 years from the production date. The expiring date and sterilization methods are clearly indicated on the pack. The product shelf life is ensured if the product is stored and transported in compliance with the environmental condition stated on the pack and on the delivery boxes.

Clinical Performance Data: [(807.92(b)(2)]
Clinical data are not required.

Conclusion: [(807.92(b)(3)]
Pikdare Pen Needles (Insupen/Insupen ORIGINAL/ Insupen ADVANCED) are concluded to be substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate device.