

510(k) Summary

THIEBAUD SAS's st'rim™, Patent, macro st'rim™, Patent, mini st'rim™, Patent and nano st'rim™, Patent

I. Submitter

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Assigned 510(k) number: BK220750
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II. Device information

Device name: st'rim™, macro st'rim™, mini st'rim™, nano st'rim™
Classification name: System, Suction, Lipoplasty
Regulation number: 21 CFR 878.5040
Device Class: Class II
Classification Panel: General & Plastic Surgery
Product code: MUU

III. Predicate information

Predicate device: st'rim™
Manufacturer: THIEBAUD SAS
510K Number: K142073

IV. Device description

The modified st'rim range™ and the predicate only differ in size and number of devices available.

The st'rim™, mini st'rim™ and nano st'rim™ sets each consist of one tissue harvest cannula, three injection (application) cannulas, two incision needles, all made of stainless steel, and a double-ended female Luer Lock compatible connector for transfer of the fat tissue from the collection syringe to an injection syringe.

The macro st'rim™ set consists of one tissue harvest cannula, three injection (application) cannulas and one incision needle all made of stainless steel. The body contacting material is medical grade stainless steel and the contact duration is limited.

All components are provided in a preformed plastic tray. The set is a sterile, single-use device.

V. Indication for use

The *st'rim*TM, *macro st'rim*TM, *mini st'rim*TM and *nano st'rim*TM fat tissue harvest and injection cannula sets are intended for use in aesthetic body contouring.

VI. Comparison of Technological Characteristics

Technological characteristics	Subject device	Predicate device
Regulatory information		
Device name	<i>nano st'rim</i> TM , <i>mini st'rim</i> TM , <i>st'rim</i> TM and <i>macro st'rim</i> TM	<i>st'rim</i> TM
510 K-number	This submission BK220750	K142073
Manufacturer	Identical	THIEBAUD SAS
Regulation	Identical	878.5040
Class	Identical	II
Product code	Identical	MUJ
Intended use		
Indications for use	<i>The st'rim</i> TM , <i>macro st'rim</i> TM , <i>mini st'rim</i> TM and <i>nano st'rim</i> TM fat tissue harvest and injection cannula sets are intended for use in aesthetic body contouring.	The <i>st'rim</i> TM fat tissue harvest and injection cannula set is intended for use in aesthetic body contouring.
Population	Identical	Adults
User	Identical	Practitioner
Technological Characteristics		
Components	<p><u><i>Nano st'rim, mini st'rim and st'rim:</i></u></p> <p>1 stainless steel collection cannula (14G) with luer lock connection for syringe connection: - 150 mm long x 2 mm diameter (<i>nano st'rim and st'rim</i>) - 90 mm long and 2 mm diameter (<i>mini st'rim</i>), - 70 mm long and 2 mm diameter (<i>mini st'rim</i>)</p> <p>3 stainless steel reinjection cannulas with hubs for syringe connection for the two <i>mini st'rim and st'rim</i>: - 40 mm long x 0.8 mm diameter (21 gauge), and - 60 mm long x 0.8 mm diameter (21 gauge) - 49 mm long x 1.1 mm diameter (19-gauge)</p> <p>3 stainless steel reinjection cannulas with hubs for syringe connection for <i>nano st'rim</i>: - 40 mm long x 0.4 mm diameter (27-</p>	<p>1 stainless steel collection cannula (14G) with luer lock connection for syringe connection (130 mm long x 2 mm diameter)</p> <p>3 stainless steel reinjection cannulas (21G) with hubs for syringe connection (Two 40 mm long x 0.8 mm diameter and one 60 mm long x 0.8 mm diameter)</p> <p>2 stainless steel incision needles (14 gauge (2 mm) and 21 gauge (0.8 mm))</p> <p>1 double-ended female luer lock stainless steel connector</p> <p>Luer lock connections are polypropylene capped</p>

Technological characteristics	Subject device	Predicate device
	gauge), and - 50 mm long x 0.6 mm diameter (23-gauge) - 60 mm long x 0.8 mm diameter (21-gauge) 2 stainless steel incision needles: - 14 gauge (2 mm), and - 21 gauge (0.8 mm) 1 double-ended female luer lock stainless steel connector Luer lock connections are polypropylene capped <i>macro st'rim:</i> 1 stainless steel collection cannula (10G) with luer lock connection for syringe connection (220 mm long x 3,5 mm diameter) 3 stainless steel reinjection cannulas with hubs for syringe connection (Two 150 mm long x 2 mm diameter (14-gauge) and one 100 mm long x 1.5 mm diameter (17-gauge)) 1 stainless steel incision needle (17-gauge (1.5 mm)) Luer lock connections are polypropylene capped	
Sterile	Identical	Yes
Sterilization method	Identical	Ethylene oxide
Shelf life	Identical	5 years
Packaging	Identical	Double sterile barrier system Device in a PETG Tray for aseptic presentation
Disposable	Identical	Yes
Single Use	Identical	Yes
Biocompatible	Identical	Yes, tested through ISO 10993-1 process

VII. Summary of non-clinical testing and risk analysis

Based on the risk analysis assessing the impact of the modification, non-clinical testing included mechanical resistance test derived from ISO 7864, chemical characterization, toxicological assessment and biocompatibility testing from ISO 10993. The testing demonstrated that the modified device and can be considered substantially equivalent to the predicate device.

VIII. Conclusion

There are no substantial differences between the modified st'rim™ range and the predicate device with respect to intended use and technological characteristics, including design, materials of manufacture, mechanical properties, and intended effect.

Therefore, the st'rim™, macro st'rim™, mini st'rim™, nano st'rim™ can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.