January 20, 2023

Quanta System, S.p.A.
Dario Bandiera
Regulatory Affairs Manager
Via Acquedotto 109
Samarate, VA 21017
Italy

Re: K223404
Trade/Device Name: Duetto Suprema; Domino Suprema; Suprema VT; Suprema VT+; Suprema 4V
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 2, 2022
Received: November 9, 2022

Dear Dario Bandiera:

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,

Jianting Wang -S

Jianting Wang
Acting 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.

Submission Number *(if known)*

K223404

Device Name

Duetto Suprema;
Domino Suprema;
Suprema VT;
Suprema VT+;
Suprema 4V

Indications for Use *(Describe)*

General intended use
Suprema Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.

Indications for use

1064 nm (pulsed)
Dermatology/Plastic Surgery:
Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis.
The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.
The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.
The laser is also indicated for the treatment of facial wrinkles.
Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
The laser is also indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types.

532 nm (pulsed)
Intended for the coagulation and hemostasis of vascular lesions.

Dermatology/Plastic Surgery:
For photocoagulation and hemostasis of vascular and cutaneous lesions in dermatology including but not limited to the following general categories: vascular lesions [angiomas, hemangiomas (port

wine), telangiectasia (facial or ex-tremities telangiectasias, venous anomalies, leg veins]; benign pigmented lesions (nevi, lentigines, chloasma, cafe au- lait, tattoos (red and green ink), verrucae, skin tags, keratoses, plaques, cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).
755 nm (pulsed)
Indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs re-growing when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

IPL 590-1200nm; 625-1200nm; 650-1200nm
Indicated for permanent hair removal.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

IPL 550-1200nm; 570-1200nm
Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.

IPL 400-1200nm
Indicated for inflammatory acne (acne vulgaris).

Integrated Skin Cooler
The intended use of the integrated cooling system in Suprema Family is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.

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.

510(k) Summary

Applicant / manufacturer:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	2nd November 2022
Model name:	Suprema Family including the following models: Duetto Suprema, Suprema VT, Suprema VT+, Suprema 4V, Domino Suprema.
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Basis for submission:	Device technical modifications
Predicate device	Evo Platform (K192160) and Chrome (K202503) manufactured by Quanta System. Suprema family devices are derived from legally marketed Evo Platform devices except for Twain IPL accessory that is the same of Chrome family.

1 Abbreviations

FW= firmware
GUI= graphical user interface
IPL= intense pulsed light
P= pulsed
SW= software

2 Device description

Suprema family includes medical laser devices for dermatology and aesthetic medicine. It is used by health care professionals (dermatologists) in professional healthcare environments for the treatment of different skin conditions and hair removal.
Suprema models differ for the installed laser sources only according to Table 1.

Table 1: Suprema family models with laser sources (*P=Pulsed mode).

	Nd: YAG 1064 nm (P*)	Nd: YAG 532 nm (P*)	Alexandrite 755 nm (P*)
Duetto Suprema	x		x
Domino Suprema			x
Suprema VT	x		
Suprema VT+	x	x	
Suprema 4V	x	x	x

Suprema devices are transportable mobile electrical equipment with a display with a graphical user interface (GUI) for user-device interaction.
Laser radiation is delivered through optical fibers connected to handpieces having fix or variable spot dimension.
The device can be optionally equipped with an integrated skin cooler. In this case, a specific housing called *Skin Cooler* handpiece is provided to provide skin cooling and housing the laser handpiece at the same time.
Configurations without optional integrated skin cooler, can be used in conjunction with *Cryo 6* skin cooler manufactured by *Zimmer GmbH* (K060395). In this case, an optional housing is provided which is called *Skin Cryo* handpiece. Laser handpieces cannot be used alone but only in conjunction to *Skin Cooler* and *Skin Cryo* handpieces.
Laser emission can be activated by the footswitch or by a finger-switch placed on *Skin Cooler* and *Skin Cryo* handpieces.
The device can be divided into four main sections:

- Power electronics: they manage power supplied to all device compartments;
- Control electronics: they mainly consist of a microcontroller board where device main FW (firmware) is resident;
- Cooling system: it cools the laser source pumping chamber and, in case of integrated skin cooling, a part of the water circulating in the hydraulic system is deviated to a chiller that cools water for skin cooling;
- Optical bench.

Suprema devices can be used in conjunction with Twain IPL and Twain 2940 devices. Twain IPL and Twain 2940 are already FDA cleared (K202503, K173002, respectively).

3 Comparison with the predicate

Suprema Family is equivalent to Evo family according to the cross-reference matrix below (Table 2), as they share the same laser wavelengths.

Table 2: Suprema vs Evo cross-reference matrix.

Suprema	*Evo*	*Sources (nm)*
Duetto Suprema	Light A Star	1064, 755 (P)
Suprema VT	Light B	1064 (P)
Suprema VT+	Light C	1064, 532 (P)
Suprema 4V	Light 4V	1064, 532, 755 (P)
Domino Suprema	Domino	755 (P)

Suprema Family is equivalent to Evo family except for Twain IPL accessory that is identical to Chrome Twain IPL (K202503) which has been considered as further predicate.
In Table 3, the main specifications of the subject device are summarized and compared to the predicates:

Table 3: Main specifications comparison table.

Specification	**Predicate**	**Subject device**
Device Name	*Evo Platform*	*Suprema Family*
K number	K192160	-
Manufacturer	Quanta System S.p.A.	Quanta System S.p.A.
Product Code	GEX	GEX
Laser Sources	Nd:YAG and Alexandrite	Nd:YAG and Alexandrite
Laser Wavelengths	☒ 1064nm pulsed ☒ 532nm pulsed ☒ 755nm pulsed	☒ 1064nm pulsed ☒ 532nm pulsed ☒ 755nm pulsed
Indications for use	General intended use: Suprema Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows. Indications for use: 1064 nm (pulsed) Dermatology/Plastic Surgery: Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. The laser is also indicated for the treatment of facial wrinkles.	The same

Specification	Predicate	Subject device
Device Name	*Evo Platform*	*Suprema Family*
	Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. The laser is also indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types. 532 nm (pulsed) Intended for the coagulation and hemostasis of vascular lesions. Dermatology/Plastic Surgery: For photocoagulation and hemostasis of vascular and cutaneous lesions in dermatology including but not limited to the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or ex-tremities telangiectasias, venous anomalies, leg veins]; benign pigmented lesions (nevi, lentigines, chloasma, cafe au- lait, tattoos (red and green ink), verrucae, skin tags, keratoses, plaques, cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size). 755 nm (pulsed) Indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs re-growing when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. IPL 590-1200nm; 625-1200nm; 650-1200nm Indicated for permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. IPL 550-1200nm; 570-1200nm Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions. IPL 400-1200nm Indicated for inflammatory acne (acne vulgaris). Integrated Skin Cooler: The intended use of the integrated cooling system in Suprema Family is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.	
Pulse width (max)	@1064 nm: 300 ms @532 nm: 50 ms	The same

Specification	Predicate	Subject device
Device Name	*Evo Platform*	*Suprema Family*
	@755 nm: 300 ms	
Fluence (max)	@1064 nm: 300 J/cm^2 @532 nm: 95 J/cm^2 @755 nm: 60 J/cm^2	The same
Spot Size	Handpieces spot diameter cleared with K192160 are: @1064 nm: 2÷24 mm @532 nm: 2÷7 mm @755 nm: 6÷24 mm Spots that have been actually placed on the market are the following: @1064 nm: 2÷5, 6, 8, 10, 12, 14, 16 @532 nm: 2÷5, 6, 7 @755 nm: 6, 8, 10, 12, 14, 16	Variable: 2÷6 mm (1 mm step) 8÷20 mm (2 mm step) Fixed: 14, 16, 18, 20, 22 mm The indicated sizes refer to the diameter (in case of round spots) or side (in case of square spots). At 1064 and 755 nm, the maximum cleared (Evo) spot area is: A=π*(24 mm/2)^2= 452 mm^2 While the maximum area of the subject device at all the wavelengths is: A=22*22 mm=484 mm^2 At 1064 nm and 755 nm the maximum spot area of the subject device is 7% larger than the maximum spot area of the predicate device. The difference is not significant and does not raise any new concern related to thermal effects, considering also that both the maximum energy and fluence available for the spot with larger sizes are lower than the ones available for the spots with the smaller sizes (see Table 4). For 532 nm the maximum spot area of the subject device is about 12 times the maximum spot area of the predicate device. The difference does not raise any new concern related to thermal effects considering that the maximum fluence available for the spot with the largest size is 28 times lower than the fluence available for the 4 mm spot (see Table 4). Thus, the possible thermal effect due to the pooling of the heat in the center of the large spot does not exceed the thermal effect directly reached through the significantly higher fluence in the small spot. The maximum

Specification	Predicate	Subject device
Device Name	*Evo Platform*	*Suprema Family*
		fluence available in the small spots is the same of the predicate device.
Repetition Rate (max)	@1064 nm: 10 Hz @532 nm: 5 Hz @755 nm: 10 Hz	The same
Skin Cooling	Three cooling levels	The same
Twain IPL		
Specification	**Predicate**	**Subject device**
Device Name	*Chrome*	*Suprema Family*
K number	K202503	-
Manufacturer	Quanta System S.p.A.	Quanta System S.p.A.
Wavelengths	650-1200 nm 625-1200 nm 590-1200 nm 570-1200 nm 550-1200 nm 400-1200 nm	The same
Pulse width (max)	40 ms	The same
Spot size	48mm x 13mm 25mm x 13mm	The same
Fluence (max)	25 J/cm^2	The same
Repetition rate	3 Hz	The same
Cooled waveguides	Three cooling levels	The same

Table 4: Correlation matrix spot size vs fluence/energy.

	532 nm	**755 nm**	**1064 nm**
Spot size diameter/side (mm)	**Fluence (J/cm2)**	**Fluence (J/cm2)**	**Fluence (J/cm2)**
2	95,0	60,0	300,0
3	95,0	60,0	300,0
4	95,0	60,0	300,0
5	66,2	60,0	300,0
6	46,0	60,0	212,3
8	25,9	60,0	119,4
10	16,6	60,0	76,4
12	11,5	48,7	53,1
14	8,4	35,7	39,0
16	6,5	27,4	29,9
18	5,1	21,6	23,6
20	4,1	17,5	19,1
22	3,4	14,5	15,8

4 Indication for use

General intended use:

Suprema Family is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.

Indications for use:

1064 nm (pulsed)
Dermatology/Plastic Surgery:
Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis.
The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.
The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.
The laser is also indicated for the treatment of facial wrinkles.
Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
The laser is also indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types.

532 nm (pulsed)
Intended for the coagulation and hemostasis of vascular lesions.

Dermatology/Plastic Surgery:
For photocoagulation and hemostasis of vascular and cutaneous lesions in dermatology including but not limited to the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or ex-tremities telangiectasias, venous anomalies, leg veins]; benign pigmented lesions (nevi, lentigines, chloasma, cafe au- lait, tattoos (red and green ink), verrucae, skin tags, keratoses, plaques, cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

755 nm (pulsed)
Indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs re-growing when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

IPL 590-1200nm; 625-1200nm; 650-1200nm
Indicated for permanent hair removal.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

IPL 550-1200nm; 570-1200nm
Indicated for photocoagulation of dermatological vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.

IPL 400-1200nm
Indicated for inflammatory acne (acne vulgaris).

Integrated Skin Cooler:

The intended use of the integrated cooling system in Suprema Family is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesion, and to reduce the potential side effects of laser treatments.

5 Non-clinical tests

The present device was subject to non-clinical testing according to the following standards (Table 5):

Table 5: Applied standards.

Standard	Discussion
IEC 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1 tests have been repeated on Suprema due to differences in the enclosure (fans/grids positioning) and differences in some critical components.
IEC 60601-1-2: 2014 Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2 tests have been repeated for the same reasons as above.
IEC 60601-1-6: 2010/AMD1: 2013 Collateral standard: Usability	Usability tests have been repeated due to small differences in handpieces, actuator and GUI.
IEC 62366-1: 2015/COR1: 2016 Part 1: Application of usability engineering to medical devices	
IEC 62304: 2006/AMD1: 2015 Medical device software (SW)	SW verification and validation activities have been repeated due to some differences in the SW and FW.
IEC 60601-2-22: 2007/AMD1: 2012 Particular requirements for basic safety and essential performance of surgical, cosmetic etc.	IEC 60601-2-22 tests have been repeated due to some optical differences. For Twain 2940 handpiece, test reports submitted with K173002 are still valid.
IEC 60825-1: 2014 Safety of laser products – Part 1: Equipment classification and requirements	No tests necessary for compliance to this standard, only standard requirements fulfillment checking and calculations.
IEC 60601-2-57: 2011 Particular requirements for the basic safety and essential performance of non-laser light source equipment	Applicable to Twain IPL handpiece that had already be included in Chrome 510k. Test reports submitted with K202503 are still valid.
ISO 10993-1: 2018 Biological evaluation of medical devices	Tests have been repeated for tip metal part as a different material has been used.

The results of the non-clinical performance standards testing support that the subject device can be used safely and effectively.

6 Substantial equivalence discussion

Suprema devices have the same intended use of the predicate device and comparable technical specifications.

7 Conclusions

Non-clinical tests conducted support that the device can be used safely and effectively for the proposed indications for use. The differences in technological characteristics between the subject and predicate

devices do not raise new questions regarding safety and effectiveness for the proposed indications for use. Thus, the subject device is considered to be substantially equivalent to the predicate devices.