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

August 29, 2014

Alma Lasers Ltd
% Kathy Maynor
Consultant
26 Rebecca Court
Homosassa, Florida 34446

Re: K140009
Trade/Device Name: The Modified Alma Lasers XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano XL Soprano XL and Soprano ICE]
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, ILY
Dated: April 26, 2014
Received: June 3, 2014

Dear Ms. Maynor:

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" (21CFR 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,

David Krause -S

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

510(k) Number (if known):	**K140009**
Device Name:	The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}]

Intended Use

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] is intended for use in dermatologic and general surgical procedures.

Indications for Use

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] includes Diode Laser and NIR Modules

Diode Laser Modules:

The indications for use for the 810nm Modified Diode Laser Module 1.2 cm^2 include:

- The Hair Removal (HR) and Super Hair Removal(SHR) Mode is intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.(The Laser Blanch (LB) Mode)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and LB Modes)

Optional Tapered Light Guide: It is intended for the same use as the device.

The indications for use for the 810nm Modified Diode Laser Module 2 cm^2 include:

- The Hair Removal (HR) and Super Hair Removal(SHR) Mode is intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and SHR Modes)

The indications for use for the 755nm Diode Laser Module include:

- The Hair Removal (HR) and Super Hair Removal(SHR) Mode is intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.(The Laser Blanch Mode)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and Laser Blanch Modes)

NIR Modules

The Alma Lasers NIR Modules intended use is to emit energy in the near infrared (NIR) spectrum to provide topical heating. The indications for use for NIR Modules are :

- Elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness,
- The temporary relief of minor joint pain associated with arthritis,
- The temporary increase in local circulation where applied, and
- The relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

	Prescription Use	✓		AND/OR	Over-The-Counter Use	
	(Part 21 CFR 801 Subpart D)				(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

For BSA

Neil R Ogden -S
2014.08.28 14:45:04 -04'00'

Section 8 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter:	Alma Lasers, Ltd, Halamish St. POB 302 Industrial Park, 38900
Contact Person:	Kathy Maynor Consultant 352-586-3113 (cell)
Summary Preparation Date:	Aug 28, 2014

II. Names

Device Names:	The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano XL, Soprano XLi and Soprano ICE]
Primary Classification Names:	Surgical Powered Light Instrument, Lamp, Infrared, Therapeutic Heating

III. Predicate Devices

K #	Predicate Device
K112031	Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the family of Soprano XL Multi-Application Platforms
K102716	Modified Alma Lasers Family of Soprano Family XL ™ Multi Application Platform (Soprano XL, Soprano XLi).
K083848	Alma Lasers Soprano XL Multi-Application Platform
K080318	Alma Lasers NIR Module
K090571	Alma Lasers Alex755 Module
K101916	Sciton Clear Scan
K083207	Quanta System Ultrawave III EX 1320

IV. Product Description

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano XL, Soprano XLi and Soprano ICE] is a modification to previously cleared Soprano Family XL ™ Multi Application Platform [Soprano XL and Soprano XLi].The relevant K number is K102716

Soprano ICE, the new addition to the family has hand pieces with multiple wavelengths, spot sizes and supports both Diode Laser and Near Infrared (NIR) Technologies. The Soprano Ice comprises of the following major components:

1. The main console unit
2. Footswitch.
3. Modules

V. Indications for Use

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] is intended for use in dermatologic and general surgical procedures.

The Indications for Use are provided in **Section 7** of this submission.

VI. Summary of Technical Characteristics

Table 1: Salient Characteristics of the modified diode 810nm module spot size 1.2 cm2 and the Predicate Devices

Parameter	**K14** Alma Lasers Modified 810nm Diode Laser Module to be used with cleared Soprano XL and XLi Platform and proposed Soprano ICE			**K112031** Alma Lasers Modified Diode Laser Module with SHR Treatment Mode used with the Soprano XL Multi-application Platforms			**K102716** Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XL™, Soprano XLi™]		**K083848** Alma Lasers Soprano XL Multi-Application Platform
Product Code & Regulation No.	GEX 21 CFR 878.4810			GEX 21 CFR 878.4810			GEX 21 CFR 878.4810		GEX 21 CFR 878.4810
Diode Module Modes	*SHR	*HR	*LB	SHR	HR	LB	HR	LB	HR
Laser Wavelength [nm]	810(nominal)			810(nominal)			810(nominal)		810(nominal)
Light/Laser Source	Diode			Diode			Diode		Diode
Spot Size[mm*mm] or [cm^2]	12*10 or 1.2, optional 6mm round tapered light guide tip			12*10 or 1.2			12*10 or 1.2		12* 10 or 1.2
Fluence (Energy Density) [J/cm^2]	2-20	2-120	Up to 40	≤10	≤120	≤80	≤ 120	≤80	≤120
Rep Rate [Hz]	5-10	0.5-3	2	≤10	≤3		≤3		≤3
Pulse Duration [ms]	3.3-200			≤20	5-200		5-200		5-200
Tissue Cooling	Contact continuous, thermo-electrical			Contact continuous, thermo-electrical			Contact continuous, thermo-electrical		Contact continuous, thermo-electrical
How Supplied	Non-sterile, cleanable			Non-sterile, cleanable			Non-sterile, cleanable		Non-sterile, cleanable
Exposure Indicator	Audible & visual indicator			Audible & visual indicator			Audible & visual indicator		Audible & visual indicator
Compatible Laser System	Family of Soprano XL, XLi (cleared) & proposed Soprano ICE			Family of Soprano XL and XLi Multi Application			Family of Soprano XL and XLi Multi Application Platforms		Soprano XL System
Dimensions [inches]	6.69*4.8*1.9			6.75*5.75*2.5			6.75*5.75*2.5		6.75*5.75*2.5
User Interface	12" LCD touch screen			12" LCD touch screen			8" LCD touch screen		8" LCD touch screen
Indications for Use	Permanent reduction in hair regrowth *		Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction		Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction	Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction
	Indicated for use on all Skin Types (Fitzpatrick Skin Types I-VI), including tanned skin * SHR-Super Hair Removal, HR-Hair Removal , LB-Laser Blanche								
	** Permanent Reduction in hair regrowth is defined as the long -term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.								

Table 2: Salient Characteristics of the modified diode 810nm module spot size 2 cm2 and the Predicate Devices

Parameter	**K13** Alma Lasers Modified 810nm Diode Laser Module to be used with cleared Soprano XL and XLi Platform and proposed Soprano ICE		**K112031** Alma Lasers Modified Diode Laser Module with SHR Treatment Mode used with the Soprano XL Multi-application Platforms			**K102716** Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XLTM, Soprano XLiTM]		**K083848** Alma Lasers Soprano XL Multi-Application Platform
Product Code & Regulation No.	GEX 21 CFR 878.4810		GEX 21 CFR 878.4810			GEX 21 CFR 878.4810		GEX 21 CFR 878.4810
Diode Module Modes	SHR	HR	SHR	HR	LB	HR	LB	HR
Laser Wavelength [nm]	810(nominal)		810(nominal)			810(nominal)		810(nominal)
Light/Laser Source	Diode		Diode			Diode		Diode
Spot Size[mm*mm] or [cm2]	20*10 or 2		12*10 or 1.2			12*10 or 1.2		12* 10 or 1.2
Fluence (Energy Density) [J/cm2]	Up to 20	Up to 60	≤10	≤120	≤80	≤ 120	≤80	≤120
Rep Rate [Hz]	5-10	0.5-3	≤10	≤3		≤3		≤3
Pulse Duration [ms]	3.3-200		≤20	5-200		5-200		5-200
Tissue Cooling	Contact continuous, thermo-electrical		Contact continuous, thermo-electrical			Contact continuous, thermo-electrical		Contact continuous, thermo-electrical
How Supplied	Non-sterile, cleanable		Non-sterile, cleanable			Non-sterile, cleanable		Non-sterile, cleanable
Exposure Indicator	Audible & visual indicator		Audible & visual indicator			Audible & visual indicator		Audible & visual indicator
Compatible Laser System	Family of Soprano XL, XLi (cleared) & Soprano Ice		Family of Soprano XL and XLi Multi Application			Family of Soprano XL and XLi Multi Application Platforms		Soprano XL System
Dimensions [“]	6.69*4.8*1.9		6.75*5.75*2.5			6.75*5.75*2.5		6.75*5.75*2.5
User Interface	12" LCD touch screen		12" LCD touch screen			8" LCD touch screen		8" LCD touch screen
Indications for Use	Permanent reduction in hair regrowth*	Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction		Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction	Treatment of benign vascular and pigmented lesions	Hair Removal, Permanent hair reduction
	Indicated for use on all Skin Types (Fitzpatrick Skin Types I-VI), including tanned skin							
	*Permanent Reduction in hair regwoth is defined as the long -term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen							

Table 3-1: Salient Characteristics of 755nm diode module and the predicate devices

Parameter	**K13** **Alma Lasers 755nm Diode Module**			**K090571** Alma Lasers ALEX755 Module		**K083207** **Quantum Ultrawave III**
Product Code & Regulation No.	GEX 21 CFR 878.4810			GEX 21 CFR 878.4810		GEX 21 CFR 878.4810
Intended Use	HR and SHR Permanent reduction in hair regrowth*	LB Mode: Treatment of benign vascular and pigmented lesions		HR and SHR Mode :Hair removal and permanent hair reduction	Treatment of benign vascular and pigmented lesions	Intended for coagulation and hemostatis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I-VI, including suntanned skin types. Also indicated for pigmented Lesions and wrinkles.
Indicated for	all Skin Types (Fitzpatrick skin types I-VI), including tanned skin					all skin types (Fitzpatrick skin types I-VI), including tanned skin
Wavelength [nm]	**755**			**755**		**755**
Light/Laser Source	Diode			Long Pulse Alexandrite		Long Pulse Alexandrite
Beam Delivery	Direct			Direct		Direct
Pulse Width [msec]	3.3-200			3 - 100		3-100
Pulse Repetition Rate [Hz]	SHR: 5-10	HR: 0.5-3	LB 2	2, 4		upto 1.5
Spot Size cm2	1.5			5mm round(.79cm2)	10mm(3.14cm2)	upto 16mm
Energy Density (Fluence) [J/cm2]	2-20	2-120	Up to 25	32	8	up to 123J/cm2

. * Permanent Reduction in hair regwoth is defined as the long -term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen

Table 3-2: Salient Characteristics of 755nm diode module and the predicate device

	K13 **Alma Lasers 755nm Diode Module**	**K090571** Alma Lasers ALEX755 Module	**K101916** Sciton
Parameter			
Product Code & Regulation No.	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Intended Use	HR and SHR Mode Permanent reduction in hair regrowth * LB Mode: Treatment of benign vascular and pigmented lesions	HR and SHR Mode :Hair removal and permanent hair reduction Treatment of benign vascular and pigmented lesions	The Clearscan ALX 755nm alexandrite laser system with its accessories is indicated for stable long term or permanent hair reduction 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
Indicated for	all Skin Types (Fitzpatrick skin types I-VI), including tanned skin		all skin types (Fitzpatrick skin types I-VI), including tanned skin
Wavelength [nm]	**755**	**755**	**755**
Light/Laser Source	Diode	Long Pulse Alexandrite	Long Pulse Alexandrite
Beam Delivery	Direct	Direct	Direct
Pulse Width [msec]	3.3-200	3 - 100	Up to 200msec
Pulse Repetition Rate [Hz]	SHR: 5-10 HR: 0.5-3 LB 2	2, 4	unk
Spot Size cm2	1.5	5mm round(.79cm2) 10mm(3.14cm2)	3mm, 6mm single spot, up to 30mm x 30mm scanned area
Energy Density (Fluence) [J/cm2]	2-20 2-120 Up to 25	32 8	Up to 140j/cm^2

* Permanent Reduction in hair regrowth is defined as a long -term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen

Table 4: Salient Characteristics of Alma Lasers NIR Large Module and the predicate devices

Parameter	**K13** **Alma Lasers NIR LargeModule**	**K080318** **Alma Lasers NIR Module**	**K050370** Palomar LuxIR Hand piece	**K042165** Cutera Titan Tabletop Product **K033768** – Altus Medical Optional Infrared Handpiece*
Product Code & Regulation No.	ILY 21CFR 890.5500	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500
Wavelength [nm]	1300	800-1,800	800-1,800 (Cleared) 850-1350 (marketing material)	850-3,000 (filtered 1,100-1,800)
Lamp Type	Quartz Tube	Quartz tube	Quartz tube	Quartz tube
Intended Use	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature
Indications for Use	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
Power Control	Time control	Time control	Time control	Exposure time
Mode **Fluence [J/cm^2]**	Pulsed 0.55-5.5	Pulsed 5.5	Pulsed Up to 100	Pulsed 5 – 65
Pulse Width [sec]	1-5	1 - 5	2.5 – 5	Not available
Spot Size [mm*mm] or cm^2]	18	60 x 30	12 x 28	10 x 15; 10 x 30
Cooling	Contact cooling Thermo-electric (TEC)	Contact cooling Thermo-electric (TEC)	Contact Cooling	Temperature regulated contact cooling
Treatment Mode	In-motion	In-motion	Stationary	Stationary
Exposure Indicator	Audible & visual indicator	Audible & visual indicator	Not available	Audible tone and LED indicator
How Supplied	Non-sterile, cleanable	Non-sterile, cleanable	Non-sterile, cleanable	Non-sterile, cleanable
Module Dimensions	190*80*56mm (L*W*H)	190*80*56mm (L*W*H)	Not Available	Not Available

Table 5: Salient Characteristics of Alma Lasers NIR Small Module and the predicate devices

Parameter	**K13** **Alma Lasers NIR Small Module**	**K080318** **Alma Lasers NIR Module**	**K050370** Palomar LuxIR Hand piece	**K042165** Cutera Titan Tabletop Product **K033768** – Altus Medical Optional Infrared Handpiece*
Product Code & Regulation No.	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500
Wavelength [nm]	1300	800-1,800	800-1,800 (Cleared) 850-1350 (marketing material)	850-3,000 (filtered 1,100-1,800)
Lamp Type	Quartz tube	Quartz tube	Quartz tube	Quartz tube
Intended Use	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature
Indications for Use	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
Power Control	Time control	Time control	Time control	Exposure time
Mode	Pulsed	Pulsed	Pulsed	Pulsed
Fluence [J/cm²]	.55-5.5	5.5	Up to 100	5 – 65
Pulse Width [sec]	1-5	1 - 5	2.5 – 5	Not available
Spot Size [mm*mm] or [cm²]	6.4	60 x 30	12 x 28	10 x 15; 10 x 30
Cooling	Contact cooling Thermo-electric (TEC)	Contact cooling Thermo-electric (TEC)	Contact Cooling	Temperature regulated contact cooling
Treatment Mode	In-motion	In-motion	Stationary	Stationary
Exposure Indicator	Audible & visual indicator	Audible & visual indicator	Not available	Audible tone and LED indicator
How Supplied	Non-sterile, cleanable	Non-sterile, cleanable	Non-sterile, cleanable	Non-sterile, cleanable

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] is substantially equivalent to the predicate devices. Additional safety testing was done as discussed in **Section 18** of this submission.

The Soprano ICE was tested by a certified testing laboratory according to:

IEC 60601-1: 1988+A1:1991+A2:1995: Medical Electrical Equipment Part 1: General Requirements for basic safety and essential performance;

IEC 60601-1-2: Medical electrical equipment: Part 1-2: General requirements for safety- Collateral Standard: Electromagnetic compatibility - Requirements and tests (2001 + A1(4));

IEC 60601-2-22:1995 Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment 1995; and

IEC 60825-1:2007 (2nd edition) Safety of Laser Products-Part 1: Equipment Classification and Requirements.

The software was documented, verified and validated (test reports in submission) in accordance with IEC 62304:2006 – Medical Device Software: Software Life Cycle Processes and ISO 14971:2012 – Medical Devices: Application of Risk Management to Medical Devices.

The optional tapered light guide was verified and validated (test reports in submission) for operation and safety in accordance with the design control and quality system principles of ISO 13485: 2012 – Medical Devices: Quality Management Systems and FDA federal regulation 21 CFR 820.

VIII. Conclusion

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] was found to be substantially equivalent to the predicate devices.

The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi} and Soprano ^{ICE}] shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.