LUMENIS®

510(K) SUMMARY

MAR 2 4 2013

FiberLase Endure CO2 Fiber

510(k) Number K 130164

Applicant's Name: Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park
Yokneam 20692 Israel
Tel. (972)4-959-9000
Fax: (9724-959-9050

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***FiberLase Endure CO2 Fiber***

Device Type: ***CO2 Laser fiber***

Preparation Date: January 20, 2013

Classification: **Regulatory Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Regulation No: 21 CFR 878.4810
Class: II
Classification Panel: General & Plastic Surgery

Device Description:

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The ***FiberLase Endure CO2 Fiber*** is a hollow, semi rigid, light-conducting delivery fiber, 2 meter length, designed to transmit laser energy from the CO2 laser system to the treatment site. The fiber also transmits a low power red diode or helium neon laser aiming beam to assist in targeting the tissue to be treated.

Intended Use Statement:

The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
FiberLase CO2 Laser WaveGuide	K100384	April 12 , 2010

Performance Standards

FiberLase Endure CO2 Fiber was tested and complies with the following standards:

- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- AAMI TIR30:2001 Product adoption and process equivalency for ethylene oxide sterilization
- ISO 14971-1:2007 Risk management for medical devices
- IEC 60601-2-22 ed3.0:2007 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1:2007 – Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide
- ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products — Moist Heat.

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A detailed description follows in **Section 14.**

Performance Testing

Performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the cleared predicate device.

Comparison with the Predicate Devices

The ***FiberLase Endure CO2 Fiber*** is a modification to its predicate device, the FDA-cleared Lumenis Fiberlase CO2 laser WaveGuide (K100384).

The intended use of the ***FiberLase Endure CO2 Fiber*** is identical to the intended use of its predicate.

Both the ***FiberLase Endure CO2 Fiber*** and the Lumenis Fiberlase CO2 laser WaveGuide systems are fibers that transmit laser energy from the laser system to the treatment site. Both devices are comprised of a laser connector and a 2 meter long delivery fiber.

The structures, the materials and the dimensions of the ***FiberLase Endure CO2 Fiber*** are identical to the cleared Lumenis Fiberlase CO2 laser WaveGuide fiber.

The minor difference between the ***FiberLase Endure CO2 Fiber*** System and its predicate device is an addition of an Autoclave sterilization method for reprocessing the fiber instead of single use ETO. The minor differences do not raise any new questions of safety or efficacy. Moreover, performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the predicate device. Thus, the ***FiberLase Endure CO2 Fiber*** is substantially equivalent to Lumenis FiberLase CO2 Laser WaveGuide (K100384).

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

Lumenis, Limited
% Qsite
Mr. Yoram Levy
General Manager
31 Haavoda Street
Binyamina, Israel 30500

March 24, 2012

Re: K130164

Trade/Device Name: FiberLase Endure CO2 Fiber
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: March 06, 2013
Received: March 11, 2013

Dear Mr. Levy:

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.

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

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130164

Device Name: *FiberLase Endure C02 Fiber*

Indications for Use:

The *FiberLase Endure C02 Fiber* is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. *FiberLase Endure C02 Fiber* is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

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

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

Neil R Ogden
2013.03.22 16:12:33 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number _K130164_____

K130164

v.1

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

Lumenis, Limited
% Qsite
Mr. Yoram Levy
General Manager
31 Haavoda Street
Binyamina, Israel 30500

March 24, 2012

Re: K130164

Trade/Device Name: FiberLase Endure CO2 Fiber
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: March 06, 2013
Received: March 11, 2013

Dear Mr. Levy:

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.

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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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Xin (Sofia) Tan, Ph.D.
Branch Chief Sign-Off	Neil R.P. Ogden, MS
Division Sign-Off	Peter D. Rumm -S 2013.03.25 22:15:12 -04'00'

f/t:XNT:kdm:3/25/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130164

Device Name: *FiberLase Endure C02 Fiber*

Indications for Use:

The *FiberLase Endure C02 Fiber* is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. *FiberLase Endure C02 Fiber* is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Prescription Use: __X___ 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)

Neil R Ogden -S
2013.03.22 16:12:33 -04'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number _K130164_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 11, 2013

LUMENIS LTD.
C/O QSITE
31 HAAVODA ST.
BINYAMINA
ISRAEL 30500
ATTN: YORAM LEVY

510k Number: K130164

Product: FIBERLASE ENDURE CO2 FIBER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

8

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Monday, March 11, 2013 6:30 PM
To: Yoram@qsitemed.com
Cc: DCCLetters
Subject: K130164/S001 ACK LETTER
Attachments: CrystalViewerCACMYO0K.rtf

Tracking:	**Recipient**	**Delivery**
	Yoram@qsitemed.com	
	DCCLetters	Delivered: 3/11/2013 6:30 PM

9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 30, 2013

LUMENIS LTD.
C/O QSITE
31 HAAVODA ST.
BINYAMINA
ISRAEL 30500
ATTN: YORAM LEVY

510k Number: K130164

Received: 1/29/2013

Product: FIBERLASE ENDURE CO2 FIBER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

LUMENIS
Enhancing Life. Advancing Technology.

K130164

January 21, 2013
Food and Drug Administration
Center for Medical Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2534
Silver Spring MD 20990
USA

Re: **Traditional Premarket Notification for the Lumenis *FiberLase Endure* eCopy Cover Letter**

Dear Madam/Sir:

In accordance with the eCopy Program for Medical Device Submissions Lumenis, ("the Company") is submitting the enclosed Traditional 510(k) Notification (21 CFR 807.90(e)) eCopy that escorts the printed hard copy of the same submission at least ninety days before the Company intends to market in the United States the **FiberLase Endure** System.

The eCopy is an exact duplicate of the paper copy.
This letter is written following an ecopy hold letter from January 8, 2013.

As required by MDUFMA of 2002, a copy of the Medical Device User Fee Cover Sheet (Payment Identification Number **MD6066445-956733** is provided in Section 1 of this application.
Presented below is a summary of applicable information related to this submission. Detailed information is provided in Sections 1 to 16 of the submission.

Applicant Name:

Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park
Yokneam 20692 Israel
Tel. (972)4-959 9000
Fax: (9724-959 9050

Contact Person:

Yoram Levy
Haavoda 31,
Binyamina 30500
Israel
Phone: (972)4-638-8837
Fax: (972)4-638-0510
E-mail: Yoram@qsitemed.com

LUMENIS®
Enhancing Life. Advancing Technology.

Trade Name: Lumenis **FiberLase Endure**

Please direct any correspondence concerning this submission to Yoram Levy of QSite, Lumenis regulatory consultant, at Yoram@qsitemed.com, Tel (972)4-638-8837 or Fax (972)4-638-0510. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile to (972)4-638-0510 or by Email.

Sincerely,

Yoram Levy
Lumenis Ltd. QA/RA Consultant

Special 510(k) Submission

FiberLase Endure CO2 Fiber

Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park
Yokneam 20692 Israel
Tel. (972)4-959 9000
Fax: (9724-959 9050

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Special 510(k) PREMARKET NOTIFICATION CHECKLIST

Item		Comments
1.	510(k) Checklist	
2.	User fee Cover sheet Form	See 510(k) notice section A
3.	CDRH Submission Cover Sheet	See 510(k) notice section B
4.	Cover letter	See 510(k) notice section C
5.	PMA (Premarket Approval) cover page	NA – this is not a class III device
6.	PMN (Premarket Notification) checklist	See 510(k) notice page 3
7.	Table of contents	See 510(k) notice page i
8.	**Indication for Use Statement**	See 510(k) notice section 1
9.	**510(k) Summary**	See 510(k) notice section 2
10.	a) Administrative information (Applicant's Name, Contact Person …)	See 510(k) notice section 2
11.	b) Name of the device (classification, Trade Name)	See 510(k) notice section 2
12.	c) Equivalence devices	See 510(k) notice section 2
13.	d) Description of the device	See 510(k) notice section 2
14.	e) Intended use	See 510(k) notice section 2
15.	f) Summary of the technological characteristics	See 510(k) notice section 2
16.	g) Performance data – non clinical	See 510(k) notice section 2
17.	h) Performance data – clinical	See 510(k) notice section 2
18.	i) Conclusions drawn from the non clinical and clinical	See 510(k) notice section 2
19.	**Truthful and Accuracy Statement**	See 510(k) notice section 3
20.	**Class III Summary and Certification**	NA - this is not a class III device
21.	**Financial Certification or Disclosure Statement**	See 510(k) notice section 4
22.	**Declaration of Conformity and Summary Reports**	See 510(k) notice section 5
23.	**Executive Summary**	See 510(k) notice section 6
24.	a) Description of the device, including the indications for use and technology	See 510(k) notice section 6
25.	b) Device comparison	See 510(k) notice section 6
26.	c) Summary for any performance testing in the	See 510(k) notice section 6

	submission	
27.	**Device description**	See 510(k) notice section 7
28.	a) General description	See 510(k) notice section 7
29.	b) Device performance specification	See 510(k) notice section 7
30.	c) Functional description	See 510(k) notice section 7
31.	d) HW description	See 510(k) notice section 7
32.	e) Device design requirements	See 510(k) notice section 7
33.	f) Diagrams, dimensions, schematics drawing and photos	See 510(k) notice section 7
34.	g) Patient contacting components and their respective materials	See 510(k) notice section 7
35.	**Substantial equivalence discussion**	See 510(k) notice section 8
36.	a) Predicate device, its trade name, model number, 510(k) submitter/holder, and 510(k) number	See 510(k) notice section 8
37.	b) Comparison discussion	See 510(k) notice section 8
38.	**Proposed Labeling**	See 510(k) notice section 9
39.	a) Device labels table	See 510(k) notice section 9
40.	b) Instructions Manual	See 510(k) notice section 9
41.	**Sterilization and Shelf Life**	See 510(k) notice section 10
42.	**Biocompatibility**	See 510(k) notice section 11
43.	a) Identification of material and manufacture as predicate device	See 510(k) notice section 11
44.	**Software**	See 510(k) notice section 12
45.	**Electromagnetic Compatibility and Electrical Safety**	See 510(k) notice section 13
46.	**Performance Testing - Bench**	See 510(k) notice section 14
47.	**Performance Testing - Animal**	See 510(k) notice section 15
48.	**Performance Testing - Clinical**	See 510(k) notice section 16
49.	**Other**	None

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SECTION 2- 510(K) SUMMARY 1

SECTION 3 – TRUTHFUL AND ACCURACY STATEMENT 1

SECTION 4 – FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT 1

SECTION 5 – DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS 1

SECTION 6 –EXECUTIVE SUMMARY 1

SECTION 7 – DEVICE DESCRIPTION 1

7.1. GENERAL DESCRIPTION ..... ERROR! BOOKMARK NOT DEFINED.
7.2. SYSTEM MAIN PARTS ..... ERROR! BOOKMARK NOT DEFINED.
7.3. TECHNICAL PARAMETERS ..... ERROR! BOOKMARK NOT DEFINED.

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SECTION 11- BIOCOMPATIBILITY 7

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13.1 EMC ..... ERROR! BOOKMARK NOT DEFINED.
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SECTION 14 - PERFORMANCE TESTING BENCH 1

SECTION 15 - PERFORMANCE TESTING ANIMAL 1

SECTION 16 - PERFORMANCE TESTING CLINICAL 1

ATTACHMENTS 1-13

Section A – Medical Device User Fee Cover Sheet

LUMENIS®

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LUMENIS LTD
New Ind. Park
Yokneam 20692
IL

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Jace McLane
2.1 E-MAIL ADDRESS
regulatory.affair@lumenis.com
2.2 TELEPHONE NUMBER (include Area code)
801-6562328
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4) 09-Jan-2013

Form FDA 3601 (01/2007)

Section B – Premarket Review Submission Cover Sheet

Section C – 510k Cover Letter

January 20, 2013

Food and Drug Administration

Center for Medical Devices and Radiological Health

Office of Device Evaluation

Document Mail Center (HFZ-401)

9200 Corporate Boulevard

Rockville, Maryland 20850 USA

Re: **Special Premarket Notification 510(k) Notification**

For *FiberLase Endure CO2 Fiber*

Dear Madam/Sir:

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and with the Code of Federal Regulations, 21 CFR 807, Subpart E, Lumenis Ltd. ("Lumenis" or "the Company"), hereby submits a special 510(k) Premarket Notification for ***FiberLase Endure CO2 Fiber.***

For the convenience of reviewers, the Agency's "Screening Checklist for All Premarket Notifications" is included in this submission. The checklist identifies the sections within this submission where the required information is located.

As required by MDUFMA of 2002, a copy of the Medical Device User Fee Cover Sheet (Payment Identification Number (b) (4) is provided in Section A of this application.

Presented below is a summary of applicable information related to this submission. Detailed information is provided in Sections 1 to 16 of the submission.

Applicant Name:	Lumenis Ltd. 13 Hayetzira Street Yokneam Industrial Park Yokneam 20692 Israel Tel. (972)4-959-9000 Fax: (9724-959-9050
Contact Person:	Yoram Levy, Qsite 31 Haavoda St. Binyamina, ISRAEL Tel: (972)4-638-8837 Fax: (972)4-638-0510
Device Trade Name:	***FiberLase Endure CO2 Fiber***
Device Type:	CO2 Laser fiber
Classification:	**Regulation Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology **Product Code:** GEX **Regulation No:** 21 CFR 878.4810 **Class:** II **Classification Panel:** General & Plastic Surgery
Indications for Use:	The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Predicate device:	**FiberLase CO2 Laser WaveGuide (K100384)** **Regulation Number:** 21 CFR 878.4810 **Regulation Name**: Laser surgical instrument for use in general and plastic surgery and in dermatology **Regulatory Class:** II **Product Code:** GEX
Type of submission:	Special 510k

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Confidentiality: (b) (4)

(b) (4)

We trust that the information contained in this 510(k) Notification will be sufficient to enable FDA to find that the ***FiberLase Endure CO2 Fiber*** is substantially equivalent to its predicate device.

Please direct any correspondence concerning this submission to Yoram Levy of QSite, Lumenis regulatory consultant, at Yoram@qsitemed.com, Tel (972)4-638-8837 or Fax (972)4-638-0510. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile to (972)4-638-0510 or by Email.

Sincerely,

Yoram Levy
Lumenis Ltd. QA/RA Consultant

CC: Assaf Gelstein, Lumenis Ltd. Platform Manager

Section 1 – Indication for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ***FiberLase Endure CO2 Fiber***

Indications for Use:

The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedure**s.**

Prescription Use __X_____ 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)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
510(k) Number

Section 2- 510(k) Summary

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510(K) SUMMARY

FiberLase Endure CO2 Fiber

510(k) Number K_____

Applicant's Name: Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park
Yokneam 20692 Israel
Tel. (972)4-959-9000
Fax: (9724-959-9050

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***FiberLase Endure CO2 Fiber***

Device Type: ***CO2 Laser fiber***

Preparation Date: January 20, 2013

Classification: **Regulatory Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Regulation No: 21 CFR 878.4810
Class: II
Classification Panel: General & Plastic Surgery

Device Description:

The ***FiberLase Endure CO2 Fiber*** is a hollow, semi rigid, light-conducting delivery fiber, 2 meter length, designed to transmit laser energy from the CO2 laser system to the treatment site. The fiber also transmits a low power red diode or helium neon laser aiming beam to assist in targeting the tissue to be treated.

Intended Use Statement:

The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedure**s.**

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
FiberLase CO2 Laser WaveGuide	K100384	April 12 , 2010

Performance Standards

FiberLase Endure CO2 Fiber was tested and complies with the following standards:

- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- AAMI TIR30:2001 Product adoption and process equivalency for ethylene oxide sterilization
- ISO 14971-1:2007 Risk management for medical devices
- IEC 60601-2-22 ed3.0:2007 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1:2007 – Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide
- ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products — Moist Heat.

A detailed description follows in **Section 14**.

Performance Testing

Performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the cleared predicate device.

Comparison with the Predicate Devices

The ***FiberLase Endure CO2 Fiber*** is a modification to its predicate device, the FDA-cleared Lumenis Fiberlase CO2 laser WaveGuide (K100384).

The intended use of the ***FiberLase Endure CO2 Fiber*** is identical to the intended use of its predicate.

Both the ***FiberLase Endure CO2 Fiber*** and the Lumenis Fiberlase CO2 laser WaveGuide systems are fibers that transmit laser energy from the laser system to the treatment site. Both devices are comprised of a laser connector and a 2 meter long delivery fiber.

The structures, the materials and the dimensions of the ***FiberLase Endure CO2 Fiber*** are identical to the cleared Lumenis Fiberlase CO2 laser WaveGuide fiber.

The minor difference between the ***FiberLase Endure CO2 Fiber*** System and its predicate device is an addition of an Autoclave sterilization method for reprocessing the fiber instead of single use ETO. The minor differences do not raise any new questions of safety or efficacy. Moreover, performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the predicate device. Thus, the ***FiberLase Endure CO2 Fiber*** is substantially equivalent to Lumenis FiberLase CO2 Laser WaveGuide (K100384).

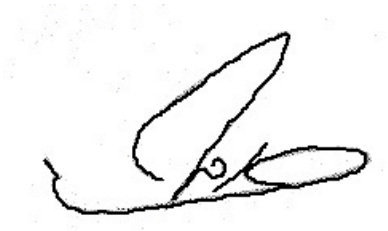
Section 3 – Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

(As Required by 21 CFR 807.87 (j))

I certify that, in my capacity as Platform Manager at Lumenis, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

Assaf Gelstein

Typed Name and Title

Lumenis Ltd.

Company

January 20, 2013

Date

Premarket Notification 510(k) Number

Section 4 – Financial Certification or Disclosure Statement

SECTION 4– FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

No clinical study was conducted. Therefore, no Financial Certification or Disclosure Statement is needed.

Section 5 – Declarations of Conformity and Summary Reports

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COMPLIANCE WITH STANDARDS

The ***FiberLase Endure CO2 Fiber*** complies with:

- IEC 60601-2-22 ed3.0:2007 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1:2007 – Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide

When combines with the laser system

In addition, the ***FiberLase Endure CO2 Fiber*** complies with the following voluntary standards (certification for compliance with the following standards follows in this section):

1. ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide.
2. ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products — Moist Heat.
3. AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
4. AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
5. ISO 14971-1:2007 Risk management for medical devices.

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VALIDATION AND VERIFICATION TESTING

A validation and verification testing report for the ***FiberLase Endure CO2 Fiber*** is attached to this submission. Testing result shows that the ***FiberLase Endure CO2 Fiber*** is safe and that it performs according to its specifications.

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STATEMENT OF CONFORMANCE TO PERFORMANCE STANDARDS

The company certifies that during the design process of ***FiberLase Endure CO2 Fiber***, it was tested according to the performance standards.

The ETO sterilization validation was done according to ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide and the Autoclave sterilization validation was done according to ANSI/AAMI/ISO 17665

The verification testing demonstrates that the functional requirement and system specifications were met.

The company also certifies that during production of ***FiberLase Endure CO2 Fiber,*** it will be validated for safety and integrity.

Signature:  Date: January 20, 2013

Ya'acov Yariv

QA Manager

Lumenis

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DECLARATION OF CONFORMITY

(Traditional 510k)

To the best of my knowledge, the verification activities, as required by the risk analysis, for the ***FiberLase Endure CO2 Fiber***, were performed by the designated individual(s) and the results demonstrated that the pre-determined acceptance criteria were met.

We, Lumenis, 13 Hayetzira Street 2066 Yokneam Industrial Park, Yokneam 2069202 Israel, declare that our facility is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

We further declare that qualified company employees performed all verification and validation activities that were required by the risk management file and the results demonstrated that the predetermined acceptance criteria were met.

Dale: *January 20, 2013*

Ya'acov Yariv
QA Manager
Lumenis

Section 6 –Executive Summary

SECTION 6 – EXECUTIVE SUMMARY

6.1. DEVICE DESCRIPTION

The ***FiberLase Endure CO2 Fiber***, is comprised of a laser connector and a 2 meter long delivery fiber. The fiber transmits laser energy from the laser system to the treatment site. The fiber also transmits a low-level red diode laser or helium-neon laser aiming beam to assist in targeting the tissue to be treated.

The ***FiberLase Endure CO2 Fiber***, is a hollow, semi rigid, light-conducting tube designed to operate at the wavelengths of 10.6 µm and 0.635 µm. These wavelengths correspond to the output of the CO2 laser device and the red-diode or helium-neon aiming beam.

The ***FiberLase Endure CO2 Fiber***, is a modification to the market-cleared Lumenis FiberLase CO2 Laser WaveGuide, which was cleared on April 12 2010, under K100384. The primary difference between the modified ***FiberLase Endure CO2 Fiber***, and the market-cleared Lumenis FiberLase CO2 Laser WaveGuide is:

- Changing the fiber from single- to multi-use by Addition of an Autoclave sterilization method for reprocessing the fiber

The modified ***FiberLase Endure CO2 Fiber*** has undergone changes that do not affect the fiber's intended use. In addition, the changes were validated to demonstrate that the modified fiber is substantially equivalent to the cleared fiber and does not raise any new safety and the effectiveness questions.

6.2. INDICATIONS FOR USE

The ***FiberLase Endure CO2 Fiber***, is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber***, is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

6.3. PREDICATE DEVICE COMPARISON

The ***FiberLase Endure CO2 Fiber***, is substantially equivalent to the following predicate device:

Device Name	510k No	Date of Clearance
Lumenis FiberLase CO2 Laser WaveGuide	K100384	April 12 2010

6.3.1. Comparison Discussion:

The ***FiberLase Endure CO2 Fiber***, is a modification to its predicate device, the FDA-cleared Lumenis Fiberlase CO2 laser WaveGuide (K100384).

The ***FiberLase Endure CO2 Fiber*** has same intended use as the cleared Lumenis FiberLase CO2 Laser WaveGuide (K100384).

The ***FiberLase Endure CO2 Fiber***, System utilizes the same technology as the cleared Lumenis FiberLase CO2 Laser WaveGuide (K100384).

The fiber of the proposed system is made of the same material as the fiber of the cleared Lumenis FiberLase CO2 Laser WaveGuide (K100384).

The primary difference between the proposed ***FiberLase Endure CO2 Fiber*** and the market-cleared Lumenis FiberLase CO2 Laser WaveGuide is:

- Changing the fiber from single- to multi-use by Addition of an Autoclave sterilization method for reprocessing the fiber.

6.4. PERFORMANCE TESTING

(b) (4)

(b) (4)

6.5. CONCLUSION

(b) (4)

ATTACHMENTS TO SECTION 6

Attachment No. 1: Substantial Equivalence Comparison Table

Section 7 – Device Description

SECTION 7 – DEVICE DESCRIPTION

7.1. GENERAL DESCRIPTION

The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

The ***FiberLase Endure CO2 Fiber*** is comprised of a laser connector and a 2 meter long delivery reusable fiber. The fiber transmits laser energy from the laser system through the fiber to the treatment site. The fiber also transmits a low-level red diode or helium-neon aiming beam to assist in targeting the tissue to be treated.

The ***FiberLase Endure CO2 Fiber*** is a hollow, semi rigid, light-conducting tube designed to operate at the wavelengths of 10.6 µm and 0.635 µm. These wavelengths correspond to the output of the CO2 laser device and the red-diode or helium-neon aiming beam.

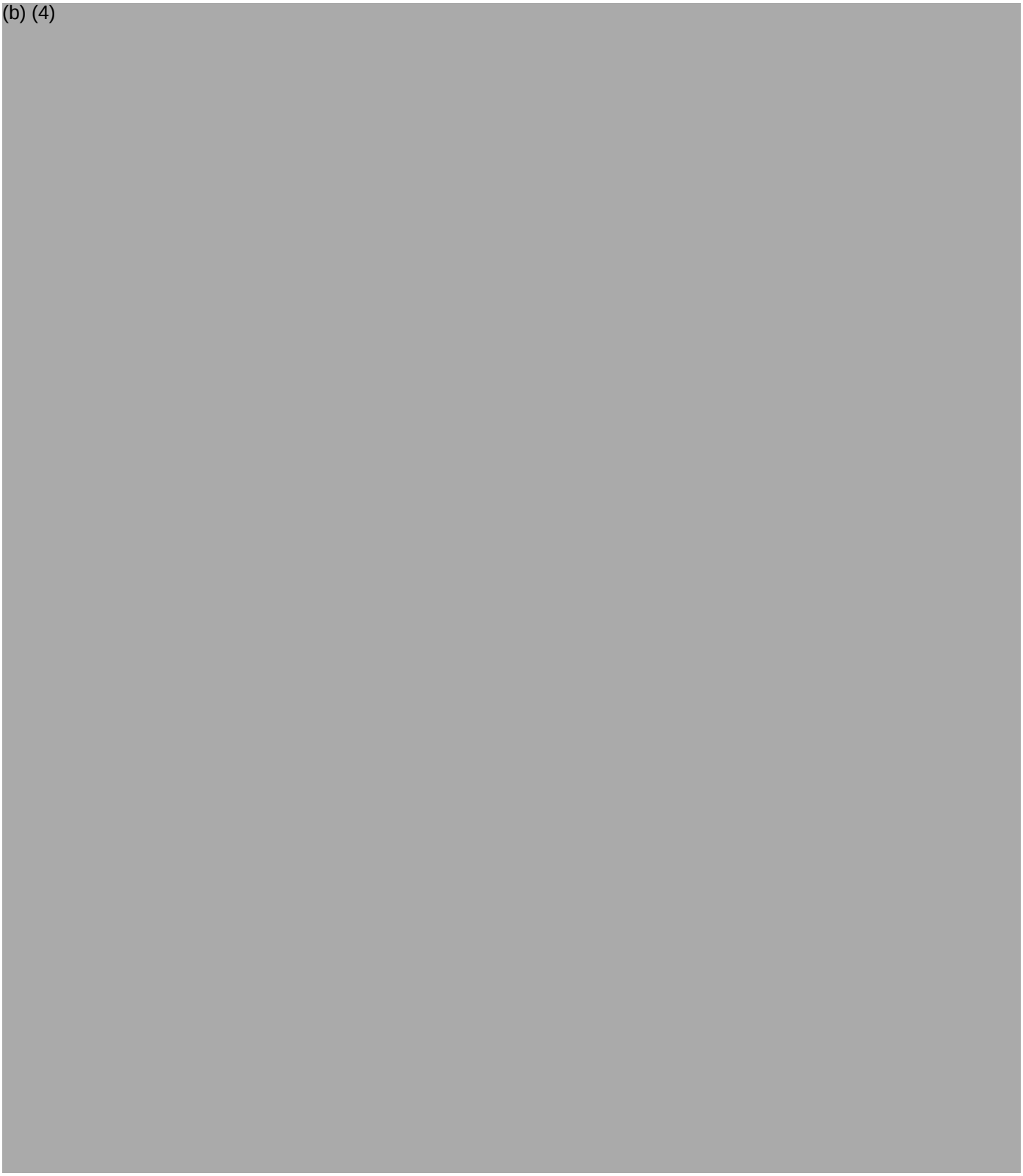
The ***FiberLase Endure CO2 Fiber*** is a modification to the market-cleared Lumenis FiberLase CO2 Laser WaveGuide, which was cleared on April 12 2010, under K100384. The primary difference between the modified **FiberLase Endure CO2 Fiber** and the market-cleared Lumenis FiberLase CO2 Laser WaveGuide is:

- Changing the fiber from single- to multi-use by Addition of an Autoclave sterilization method for reprocessing the fiber

The ***FiberLase Endure CO2 Fiber*** has undergone changes that do not affect the fiber's intended use. In addition, the changes were validated to demonstrate that the modified fiber is substantially equivalent to the original fiber and the changes do not affect the safety and the effectiveness of the fiber.

7.2. FIBERLASE ENDURE CO2 FIBER

(b) (4)



(b) (4)

7.3. PRINCIPLE OF OPERATION

(b) (4)

7.4. FIBERLASE CO_2 LASER FIBERS-ACCESSORIES

(b) (4)

(b) (4)

ATTACHMENTS TO SECTION 7

Attachment No. 2a: FiberLase Endure CO2 Fiber System User Manual

Attachment No. 2b: FiberLase Handpieces User Manual

Attachment No. 2c: FiberLase Fiber Renewal Kit User Manual

Section 8 – Substantial Equivalence Discussion

SECTION 8 - SUBSTANTIAL EQUIVALENCE DISCUSSION

8.1. PREDICATE DEVICES

The ***FiberLase Endure CO2 Fiber*** is a reusable CO2 fiber, designed to transmit laser energy from a laser system through the fiber to the treatment site.

The ***FiberLase Endure CO2 Fiber*** is substantially equivalent to the following predicate device:

Device Name	510k No	Date of Clearance
Lumenis FiberLase CO2 Laser WaveGuide	K100384	April 12 2010

8.2. COMPARISON TABLE

Substantial equivalence table, which summarizes the similarities and differences between the ***FiberLase Endure CO2 Fiber*** and its predicate device, the Lumenis FiberLase CO2 Laser WaveGuide, is attached to this submission as Attachment no. 1 and follows in this section in table 1:

Characteristics	Proposed FiberLase Endure CO2 Fiber	Lumenis FiberLase CO2 Laser WaveGuide (K100384)
Intended use	(b) (4)	Same
Product Code		Same
Regulation No.		Same

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Characteristics	Proposed FiberLase Endure CO2 Fiber	Lumenis FiberLase CO2 Laser WaveGuide (K100384)
Classification	(b) (4)	Same
Operation		Same
Basic Structure		Same
Fiber dimensions		Same. (other sizes are available)
Materials		Same
Use		Single Use
Method of Sterilization		The fiber is provided sterilized by Ethylene Oxide.
Treatment's laser		Same
Aiming beam		633 nm (Helium-Neon aiming beam)
Maximum Input Power		Same
Performance Tests		Non-clinical Laboratory performance testing was performed for the fiber functionality (e.g. Energy transmission)

Characteristics	Proposed FiberLase Endure CO2 Fiber	Lumenis FiberLase CO2 Laser WaveGuide (K100384)
Shelf Life	(b) (4)	Same
Packaging	(b) (4)	Same

Table No. 1: Comparison between the Proposed *FiberLase Endure CO2 Fiber* and the FDA cleared Lumenis FiberLase CO2 Laser WaveGuide (K100384)

8.3. COMPARISON DISCUSSION

(b) (4)

(b) (4)

8.4. CONCLUSION

(b) (4)

ATTACHMENTS TO SECTION 8

Attachment No. 3: Lumenis FiberLase CO2 Laser WaveGuide (K100384) 510(k) Summary

Section 9 - Proposed Labeling

SECTION 9 – PROPOSED LABELING

9.1 INTENDED USE

The ***Lumenis FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

9.2 INSTRUCTIONS FOR USE

FiberLase Endure CO2 Fiber*'s** User Manual is attached to this submission (Attachment No 2a). Also attached to this submission are ***FiberLase Endure CO2 Fiber's Handpieces User Manual (attachment No. 2b) and ***FiberLase Endure CO2 Fiber's*** Renewal Kit User Manual (attachment No. 2c).

9.3 DEVICE LABELS

The following describes the labeling of the ***FiberLase Endure CO2 Fiber*** (Figure No. 9-1):

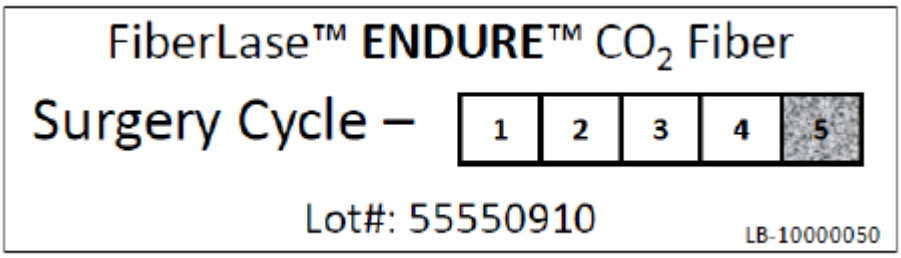


Figure 9-1: FiberLase Endure CO2 Fiber Labeling

The following describes the labeling symbols explanations of the ***FiberLase Endure CO2 Fiber*** (Figure No. 9-2):

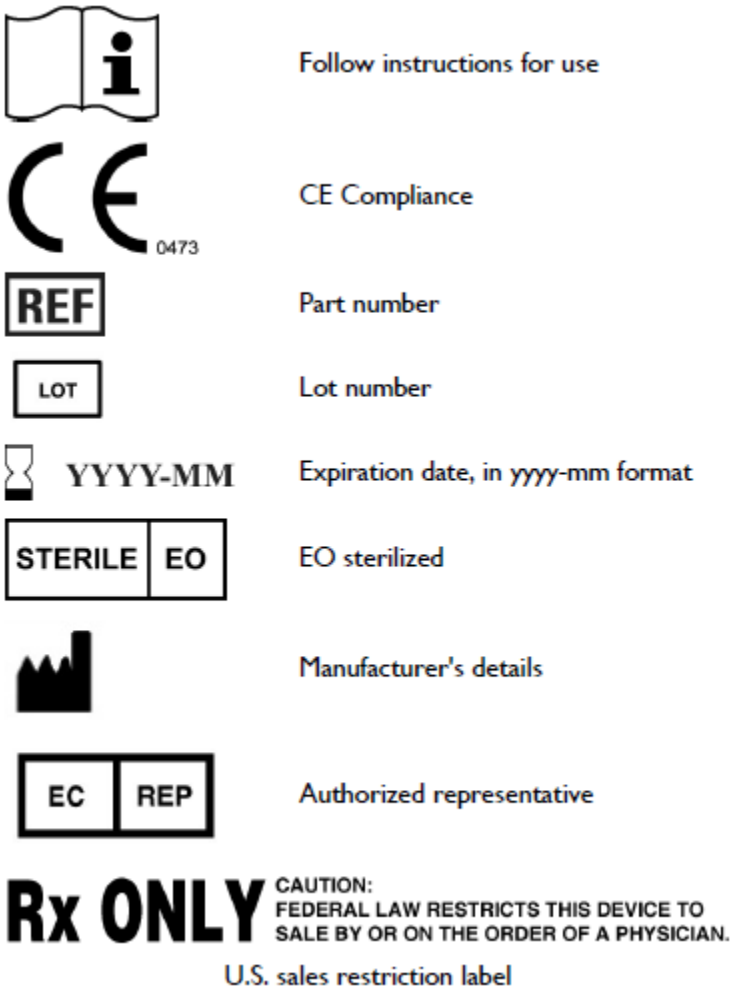


Figure 9-2: FiberLase Endure CO2 symbol explanations

ATTACHMENTS TO SECTION 9

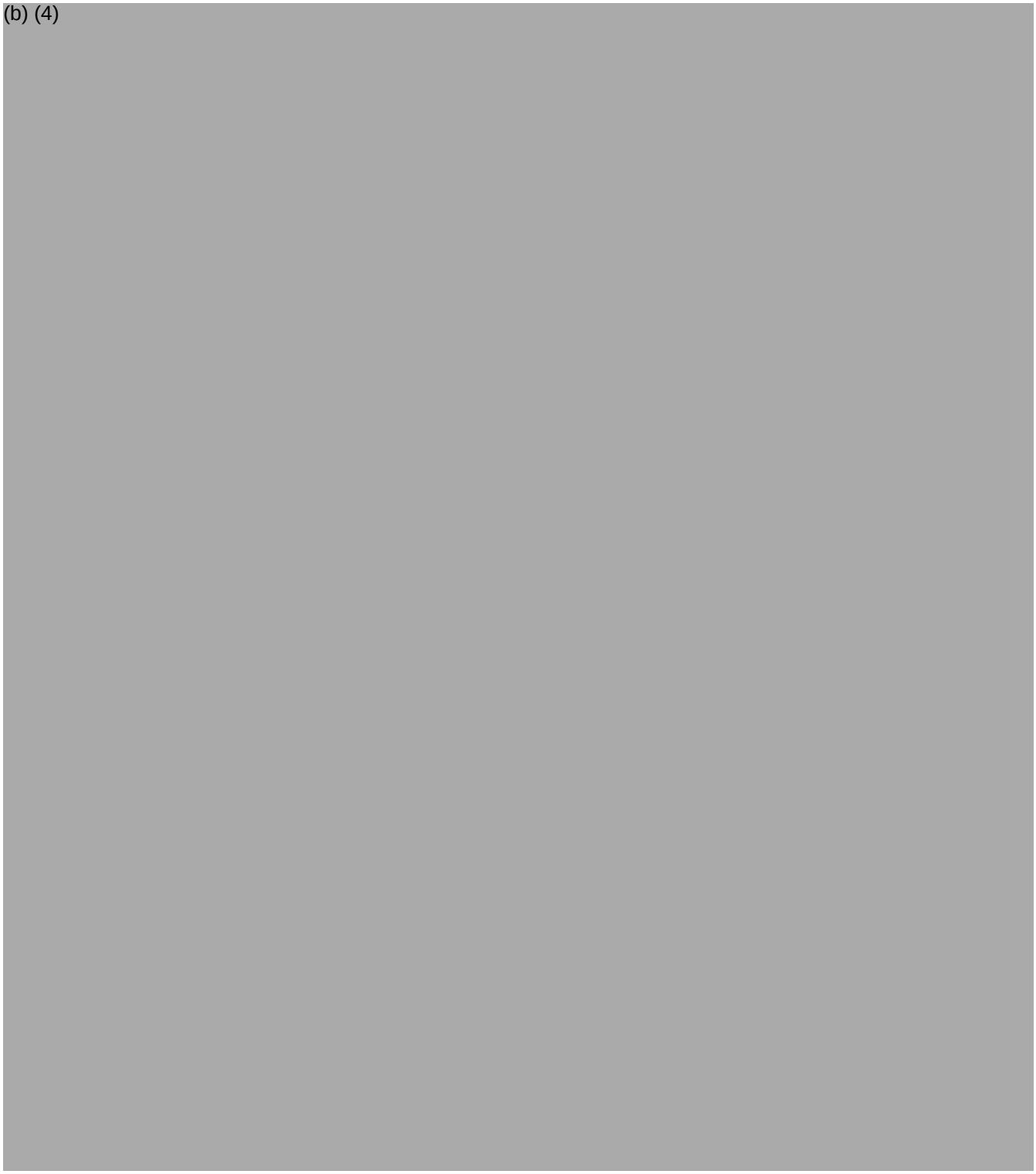
None

Section 10- Sterilization and Shelf Life

SECTION 10 – STERILIZATION AND SHELF LIFE

10.1 STERILIZATION AND CLEANING

(b) (4)



(b) (4)

10.1.2. Fiber accessories sterilization and cleaning

(b) (4)

10.2 PACKAGING

The ***FiberLase Endure CO2 Fiber*** is packed in a double Tyvek pouch, suitable for the ETO sterilization process, exactly as its predicate, the market-cleared Lumenis FiberLase CO2 laser WaveGuide (K100384).

The pouched ***FiberLase Endure CO2 Fiber*** is sent to the customer in a cardboard box. An envelope with the operating manual and warranty card is also enclosed in the main box.

The ***FiberLase Endure CO2 Fiber*** packaging has been validated as suitable for shipping in accordance with ASTM 4169-96 "standard practice for performance testing of shipping containers and system" and other standards.

After each use, the fiber and the accessories can be reused, following manual cleaning and sterilization process. The autoclave sterilization process should be performed in a pouch designed for steam sterilization or in a Lumenis' sterilization tray designed for steam sterilization (supply with the fiber), wrapped with a medical grade steam sterilization wrap (According to ISO 17665-1).

10.3. SHELF LIFE

(b) (4)

(b) (4)

ATTACHMENTS TO SECTION 10

Attachment No. 4a: Reusable fiber cleaning validation report

Attachment No. 4b: Reusable fiber Autoclave sterilization validation report

Attachment No. 4c: Reusable FiberLase Handpieces and associated devices cleaning validation report

Attachment No. 4d: Reusable FiberLase Handpieces and associated devices Autoclave sterilization validation report

Section 11- Biocompatibility

SECTION 11 – BIOCOMPTABILITY
MATERIALS AND BIOCOMPATIBILITY

The ***FiberLase Endure CO2 Fiber*** is considered as non-contact item as its predicate market-cleared Lumenis FiberLase CO2 laser WaveGuide (K100384).

In addition, the ***FiberLase Endure CO2 Fiber*** is made of the exactly the same materials as its predicate:

(b) (4)

ATTACHMENTS TO SECTION 11

None

Section 12- Software

SECTION 12: SOFTWARE

The ***FiberLase Endure CO2 Fiber*** *System* does not include software.

Section 13 - Electromagnetic Compatibility and Electrical Safety

SECTION 13: ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The ***FiberLase Endure CO2 Fiber*** *System* does not include Electrical and Electromagnetic systems.

ATTACHMENTS TO SECTION 13

None

Section 14 - Performance Testing Bench

SECTION 14 – PERFORMANCE TESTING - BENCH

14.1. Risk analysis

(b) (4)

14.2. Performance test

(b) (4)

(b) (4)

ATTACHMENTS TO SECTION 14

Attachment No. 5: FiberLase Endure CO2 Fiber Risk Analysis

Attachment No. 6: FiberLase Endure CO2 Fiber Functionality test report

Attachments No. 7: FDA Forms 3654 (Standards)

Section 15 - Performance Testing Animal

SECTION 15 – PERFORMANCE TESTING - ANIMAL

The safety and efficacy of the ***FiberLase Endure CO2 Fiber*** was shown by bench testing and performance studies.

Lumenis believes that animal study is not needed to claim safety and efficacy of the device.

ATTACHMENTS TO SECTION 15

None

Section 16 - Performance Testing Clinical

SECTION 16 – PERFORMANCE TESTING - CLINICAL

The safety and efficacy of the ***FiberLase Endure CO2 Fiber*** was shown by bench testing and performance studies.

Lumenis believes that clinical study is not needed to claim safety and efficacy of the device.

LUMENIS®

ATTACHMENTS TO SECTION 16

Attachment No. 8: FDA Form 3674 Requirements of ClinicalTrials.gov

List of Attachments

Attachment No. 1: Substantial Equivalence Comparison Table

Attachment No. 2a: FiberLase Endure CO2 Fiber System User Manual

Attachment No. 2b: FiberLase Handpieces User Manual

Attachment No. 2c: FiberLase Fiber Renewal Kit User Manual

Attachment No. 3: Lumenis FiberLase CO2 Laser WaveGuide (K100384) 510(k) Summary

Attachment No. 4a: Cleaning validation reusable CO2 FiberLase Fibers

Attachment No. 4b: Sterilization validation for reusable CO2 FiberLase Fibers

Attachment No. 4c: Cleaning validation GLP report- Reusable FiberLase Handpieces and associated devices

Attachment No. 4d: Sterilization validation GLP report - Reusable FiberLase Handpieces and associated devices Autoclave - round 1

Attachment No. 4e: sterilization validation GLP report - Reusable FiberLase Handpieces and associated devices Autoclave - round 2

Attachment No. 5: FiberLase Endure CO2 Fiber Risk Analysis

Attachment No. 6: FiberLase Endure CO2 Fiber Functionality test report

Attachment No. 7: FDA Forms 3654 (Standards)

Attachment No. 8: FDA Form 3674 Requirements of ClinicalTrials.gov

Attachment No. 1:
Substantial Equivalence Comparison Table

Attachment No. 2a:
FiberLase Endure CO2 Fiber System User Manual

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FiberLase Handpieces User Manual

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Sterilization validation for reusable CO2 FiberLase Fibers

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Cleaning validation GLP report- Reusable FiberLase Handpieces and associated devices

Attachment No. 4d:
Sterilization validation GLP report - Reusable FiberLase Handpieces and associated devices Autoclave - round I

Attachment No. 4e:
Sterilization validation GLP report - Reusable FiberLase Handpieces and associated devices Autoclave - round 2

Attachment No. 5:
FiberLase Endure CO2 Fiber Risk Analysis

Attachment No. 6:
FiberLase Endure CO2 Fiber Functionality test report

Attachment No. 7
FDA Forms 3654 (Standards)

Attachment No. 8

FDA Form 3674 Requirements of ClinicalTrials.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
January 20, 2013	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Lumenis Ltd.	(b) (4)		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(972)4-959 9000		
Street Address	FAX Number *(including area code)*		
13 Hayetzira Street	(9724-959 9050		
City	State / Province	ZIP/Postal Code	Country
Yokneam		20692	Israel
Contact Name			
Yoram Levy			
Contact Title	Contact E-mail Address		
Lumenis QA/RA Consultant	Yoram@qsitemed.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Qsite			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(972)4-638-8837		
Street Address	FAX Number *(including area code)*		
31 Haavoda St.	(972)4-638-0510		
City	State / Province	ZIP/Postal Code	Country
Binyamina		30500	Israel
Contact Name			
Yoram Levy			
Contact Title	Contact E-mail Address		
Qsite General Manager	yoram@qsitemed.com		

PSC Media Arts (301) 443-2454 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*
  change in sterilization method

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEX	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K100384	1	**FiberLase CO2 Laser WaveGuide**	1	**Lumenis**
2					
3					
4					
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

FiberLase Endure CO_2 Fiber

	Trade or Proprietary or Model Name for This Device		Model Number
1	**FiberLase Endure CO_2 Fiber**	1	
2		2	
3		3	
4		4	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: GEX

C.F.R. Section *(if applicable)*: 21 CFR 878.4810

Classification Panel: General and Plastic Surgery

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Lumenis FiberLase ENDURE CO2 fiber is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The FiberLase CO2 fiber is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: NA	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name: Lumenis Ltd.		Establishment Registration Number: NA			
Division Name *(if applicable)*		Phone Number *(including area code)*: (972)4-959 9000			
Street Address: 13 Hayetzira Street		FAX Number *(including area code)*: (9724-959 9050			
City: Yokneam		State / Province	ZIP/Postal Code: 20692	Country: Israel	
Contact Name: Yoram levy	Contact Title: Lumenis QA/RA Consultant	Contact E-mail Address: Yoram@qsitemed.com			

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: (b) (4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
(b) (4)					

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )			
Street Address		FAX Number *(including area code)*: ( )			
City		State / Province	ZIP/Postal Code	Country	
Contact Name	Contact Title	Contact E-mail Address			

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ANSI/AAMI/ISO 11135-1	ANSI/AAMI/ISO	Sterilization of health care products — Ethylene oxide	NA	2007
2	AAMI TIR30:2001	AAMI	Product adoption and process equivalency for ethylene oxide sterilization	NA	2001
	Standards No.	Standards Organization	Standards Title	Version	Date
3	IEC 60601-2-22	IEC	Medical Electrical Equipment - Part 2-22: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment.	NA	1995 amended on 2007
	Standards No.	Standards Organization	Standards Title	Version	Date
4	IEC 60825-1	IEC	Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide.	NA	2007
5	**ANSI/AAMI/ISO 17665-**1:2006	**ANSI/AAMI/ISO**	Sterilization of health care products — Moist Heat.	NA	2006
6	ISO 14971-1	ISO	Risk management for medical devices	NA	2007

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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 control

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]
AANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 0214-261		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AANSI/AAMI/ISO 17665-1:2006 STERILIZATION OF HEALTH CARE PRODUCTS - MOIST HEAT - PART 1 REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER *	SECTION TITLE	CONFORMANCE?
	N/A There were no deviations or alternate test options used	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED[L]		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED[L]		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED[L]		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[L] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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 control number.

LUMENIS®

Section C – 510k Cover Letter

LUMENIS®

K-7

K130164

FDA CDRH DMC
JAN 23 2013
Received

January 21, 2013

Food and Drug Administration
Center for Medical Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2534
Silver Spring MD 20990
USA

Re: **Special Premarket Notification 510(k) Notification**
For *FiberLase Endure CO2 Fiber*

Dear Madam/Sir:

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and with the Code of Federal Regulations, 21 CFR 807, Subpart E, Lumenis Ltd. ("Lumenis" or "the Company"), hereby submits a special 510(k) Premarket Notification for ***FiberLase Endure CO2 Fiber.***

For the convenience of reviewers, the Agency's "Screening Checklist for All Premarket Notifications" is included in this submission. The checklist identifies the sections within this submission where the required information is located.

As required by MDUFMA of 2002, a copy of the Medical Device User Fee Cover Sheet (Payment Identification Number (b) (4)) is provided in Section A of this application.

Presented below is a summary of applicable information related to this submission. Detailed information is provided in Sections 1 to 16 of the submission.

Applicant Name: Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park

Detailed information is provided in Sections 1 to 16 of the submission.

Applicant Name:	Lumenis Ltd. 13 Hayetzira Street Yokneam Industrial Park Yokneam 20692 Israel Tel. (972)4-959-9000 Fax: (9724-959-9050
Contact Person:	Yoram Levy, Qsite 31 Haavoda St. Binyamina, ISRAEL Tel: (972)4-638-8837 Fax: (972)4-638-0510
Device Trade Name:	***FiberLase Endure CO2 Fiber***
Device Type:	CO2 Laser fiber
Classification:	**Regulation Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology **Product Code:** GEX **Regulation No:** 21 CFR 878.4810 **Class:** II **Classification Panel:** General & Plastic Surgery
Indications for Use:	The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Predicate device:	**FiberLase CO2 Laser WaveGuide (K100384)** **Regulation Number:** 21 CFR 878.4810 **Regulation Name**: Laser surgical instrument for use in general and plastic surgery and in dermatology **Regulatory Class:** II **Product Code:** GEX
Type of submission:	Special 510k

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Confidentiality: Lumenis considers its intent to market the ***FiberLase Endure CO2 Fiber*** to be confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in

the Company, its advertising and law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disc losable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

We trust that the information contained in this 510(k) Notification will be sufficient to enable FDA to find that the ***FiberLase Endure CO2 Fiber*** is substantially equivalent to its predicate device.

Please direct any correspondence concerning this submission to Yoram Levy of QSite, Lumenis regulatory consultant, at Yoram@qsitemed.com, Tel (972)4-638-8837 or Fax (972)4-638-0510. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile to (972)4-638-0510 or by Email.

Sincerely,

Yoram Levy
Lumenis Ltd. QA/RA Consultant

CC: Assaf Gelstein, Lumenis Ltd. Platform Manager

* * * COMMUNICATION RESULT REPORT (MAR. 27. 2013 10:32AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : MAR. 27. 2013 10:25AM E MODE	OPTION	ADDRESS	RESULT	PAGE
4037 MEMORY TX		972 4 638 0510	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

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

Lumenis, Limited
% Qsite
Mr. Yoram Levy
General Manager
31 Haavoda Street
Binyamina, Israel 30500

March 24, 2012

Re: K130164

Trade/Device Name: FiberLase Endure CO2 Fiber
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: March 06, 2013
Received: March 11, 2013

Dear Mr. Levy:

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.

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

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

*****NOTE: This form is OPTIONAL for holds, and REQUIRED for final decisions*****

From: Reviewer Name Xin Tan

Subject: 510(k) Number K130164/S001

To: The Record

Please list CTS decision code SE

- o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- o Hold (Additional Information or Telephone Hold).
- o Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

o	NO	NSE for lack of predicate
o	NI	NSE for new intended use
o	NQ	NSE for new technology that raises new questions of safety and effectiveness
o	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
o	NP	NSE for lack of performance data
o	NS	NSE no response
o	NL	NSE for lack of performance data AND no response
o	NM	NSE pre-amendment device call for PMAs (515i)
o	NC	NSE post-amendment device requires PMAs
o	NH	NSE for new molecular entity requires PMA
o	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)?			X

Rev. 9/20/12 – added digital concurrence table

For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age<=21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days -< 2 years old)		X
Child (2 years -< 12 years old)		X
Adolescent (12 years -< 18 years old)		X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X
Nanotechnology		X
Mobile Application		X
MR Conditional		X
Device Contains Battery		X
Companion Diagnostic		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*		X

Regulation Number	**Class***	**Product Code**
21 CFR 878.4810	Class II	GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Xin Tan -S 2013.03.22 12:20:10 -04'00'
Branch Chief Sign-Off	Neil R Ogden 2013.03.22 16:14:20 -04'00'
Division Sign-Off	Peter D. Rumm -S 2013.03.25 22:06:32 -04'00'

Tan, Xin

n: Yoram Levy <yoram@qsitemed.com>
Sent: Monday, March 11, 2013 3:19 AM
To: Tan, Xin
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Dear Sofia,

I organized your questions in the two last emails in a response format so I will be able to address all of them:

(b)(4)

10

(b)(4)

Please email any farther questions that you have.

Best Regards,

Yoram
Yoram Levy, Qsite
Qsite
Global Quality for Regulatory
Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Xin TAN

Subject: 510(k) Number K130164

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page — *Attach IFU*		
510(k) Summary /510(k) Statement — *Attach Summary*		
Truthful and Accurate Statement. — *Must be present for a Final Decision*		
Is the device Class III?		
If yes, does firm include Class III Summary? — *Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		
Is this device intended for pediatric use only?		
Is this a prescription device? (If both prescription & OTC, check both boxes.)		
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		
Is clinical data necessary to support the review of this 510(k)?		
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was		

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
21 CFR 878.4810	Class II	GEX

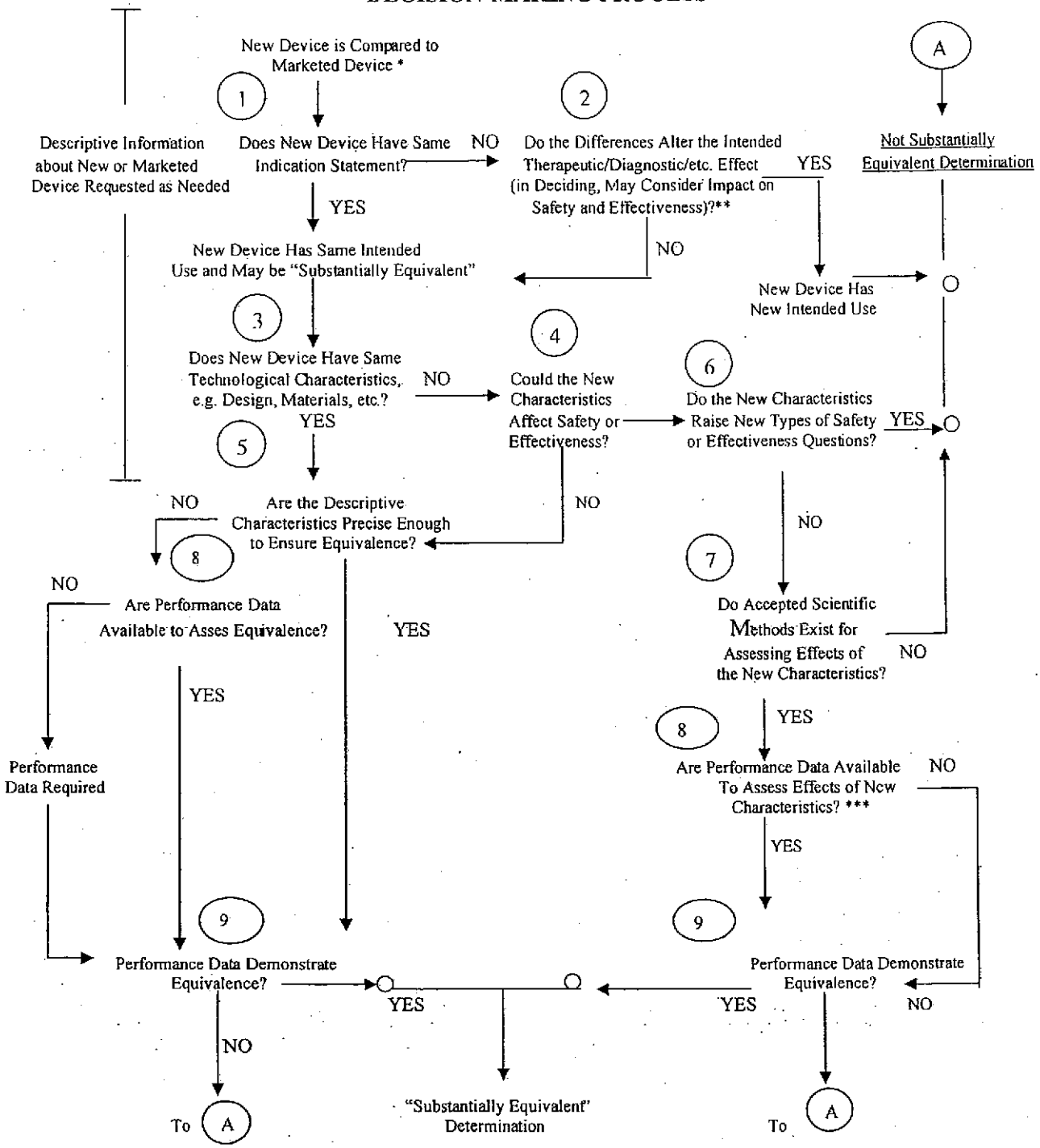
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ GS881 2/27/13
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
WO Building 66
Silver Spring, MD 20993

Premarket Notification [510(k)] Review

Special

K130164

Date: February 15, 2013
To: The Record
From: (*Sofia*) Xin Tan, Ph.D., PHYSICIST
Office: ODE
Division: DSD/GSDB1

510(k) Holder: Lumenis Ltd. (Israel)
Device Name: *FiberLase Endure CO_2 Fiber*

Contact: Yoram Levy
Qsite
31 Haavoda Street
Binyamina, ISRAEL
Phone: (972) 4-638-8837
Fax: (972) 4-638-0510
Email: yoram@qsitemed.com

I. Purpose & Submission Summary

The 510(k) holder (Lumenis Ltd.) submitted the Special Premarket Notification (K130164) to request the U.S. marketing clearance for the proposed device (*FiberLase Endure CO_2 Fiber*). The company's own FDA-cleared device (K100384 *Lumenis FiberLase CO_2 Laser WaveGuide*) is identified as the predicate. The sponsor claimed Substantial Equivalence based on the same intended use and clinical indications, same fundamental scientific technology and materials, with the only modification in changing the fiber from single to multi use by addition of an autoclave sterilization method for reprocessing the fiber.

On 14 February 2013, the sponsor sent via email a revised 510(k) Cover Letter with the added statement that there were no prior submissions for the proposed device.

II. Device Description & Indications for Use

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	

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Is the device an implant (implanted longer than 30 days)?		X	
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X		
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X	
Does the device use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user? Cleaning and autoclave sterilization methods were provided for reprocessing.	X		

(b) (4)

Submission Number	Device Name	Sponsor	Indications for Use
Subject K130164	*FiberLase Endure CO_2 Fiber*	Lumenis Ltd.	(b) (4)
Predicate K100384	*FiberLase CO_2 Laser WaveGuide*	Lumenis Ltd.	

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III. Predicate Device Comparison

(b) (4)

IV. Labeling

The sponsor provided comprehensive User Manuals for the *FiberLase Endure CO_2 Fiber*, the Handpieces, and the Renewal Kit. The FiberLase Handpieces are designed to facilitate the delivery of the fiber to the tissue treatment site. The FiberLase Fiber Renewal Kit is designed to repair the fiber tip if it becomes damaged during a surgical CO_2 laser procedure. The User Manuals also contain instructions for cleaning and sterilization. The labeling section is adequate.

V. Sterilization/Shelf Life

(b) (4)

VI. Biocompatibility

(b) (4)

VII. Software

Not applicable. The subject device does not use any software.

17

VIII. Electromagnetic Compatibility, Electrical and Mechanical Safety

Not applicable. The device does not contain Electrical and Electromagnetic Systems.

IX. Performance Testing – Bench

(b) (4)

[redacted]

X. Performance Testing – Animal

Not applicable. This submission does not include animal testing or data.

XI. Performance Testing – Clinical

Not applicable. This submission does not include human clinical testing or data.

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough? Need performance data to evaluate substantial equivalence after the addition of an autoclave (steam) sterilization procedure to reprocess the device for multi-use.		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?	X		If **NO** = Request Data

18

11. Data Demonstrate Equivalence? Questions pertaining to performance testing need to be addressed before determination on Substantial Equivalence.	?		Final Decision:

Note: Please complete the above table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

XIII. Deficiencies

(b) (4)

XIV. Recommendation

19

(b) (4)

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Device Class: Class II
Product Code: GEX

Xin Tan -S 2013.02.26 10:27:36 -05'00'

Xin Tan
Lead Reviewer

Neil R Ogden 2013.02.26 15:24:24 -05'00'

Neil Ogden
Branch Chief, ODE/DSD/GSDB1

2J

Ogden, Neil

[redacted]m: Tan, Xin
Sent: Tuesday, February 26, 2013 3:36 PM
To: 'Yoram Levy'
Cc: Ogden, Neil
Subject: Your 510(k) Submission K130164: Additional Information Required

Yoram,

(b) (4)

Performance Testing

(b) (4)

Sterilization

(b) (4)

Please submit your full response to the above deficiencies via email at your earliest convenience. Let me know if you have any questions regarding the content of this email.

Sincerely,

Sofia

XIN TAN, Ph.D. PHYSICIST
U.S. Food and Drug Administration
CDRH/OSEL/DP
10903 New Hampshire Avenue
White Oak Building 62, Room 1110
Silver Spring, Maryland 20993-0002
Phone: 301-796-2719
Fax: 301-796-9927
Email: xin.tan@fda.hhs.gov

22

K130164/S001

LUMENIS®
Enhancing Life. Advancing Technology

FDA CDRH DMC

MAR 1 1 2013

Received

March 6, 2013
Food and Drug Administration
Center for Medical Devices and Radiological Health
Office of Device Evaluation
10903 New Hampshire Avenue
White Oak, Bldg 66, Room 2534
Silver Spring MD 20990
USA

Re: **Response for the Lumenis *FiberLase Endure* eCopy Cover Letter**

Dear Madam/Sir:

In accordance with the eCopy Program for Medical Device Submissions Lumenis, ("the Company") is submitting the enclosed response for 510(k) Notification (21 CFR 807.90(e)) eCopy that escorts the printed hard copy of the same response.

The eCopy is an exact duplicate of the paper copy.

Presented below is a summary of applicable information related to this submission. Detailed information is provided in Sections 1 to 16 of the submission.

Applicant Name:

Lumenis Ltd.
13 Hayetzira Street
Yokneam Industrial Park
Yokneam 20692 Israel
Tel. (972)4-959 9000
Fax: (9724-959 9050

Contact Person:

Yoram Levy
Haavoda 31,
Binyamina 30500
Israel
Phone: (972)4-638-8837
Fax: (972)4-638-0510
E-mail: Yoram@qsitemed.com

Trade Name: Lumenis **FiberLase Endure**

Please direct any correspondence concerning this submission to Yoram Levy of QSite, Lumenis regulatory consultant, at Yoram@qsitemed.com, Tel (972)4-638-8837 or Fax (972)4-638-0510. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile to (972)4-638-0510 or by Email.

LUMENIS®
Enhancing Life. Advancing Technology

Sincerely,

Yoram Levy
Lumenis Ltd. QA/RA Consultant

LUMENIS®

Date: March 3, 2013

To: Sofia XIN TAN, Ph.D. PHYSICIST
U.S. Food and Drug Administration
CDRH/OSEL/DP
10903 New Hampshire Avenue
White Oak Building 62, Room 1110
Silver Spring, Maryland 20993-0002
USA

Subject: **Response to K130164 Fiberlase Endure CO2 Fiber Request for Additional Information**

Dear Dr. XIN TAN

(b) (4)

LUMENIS®

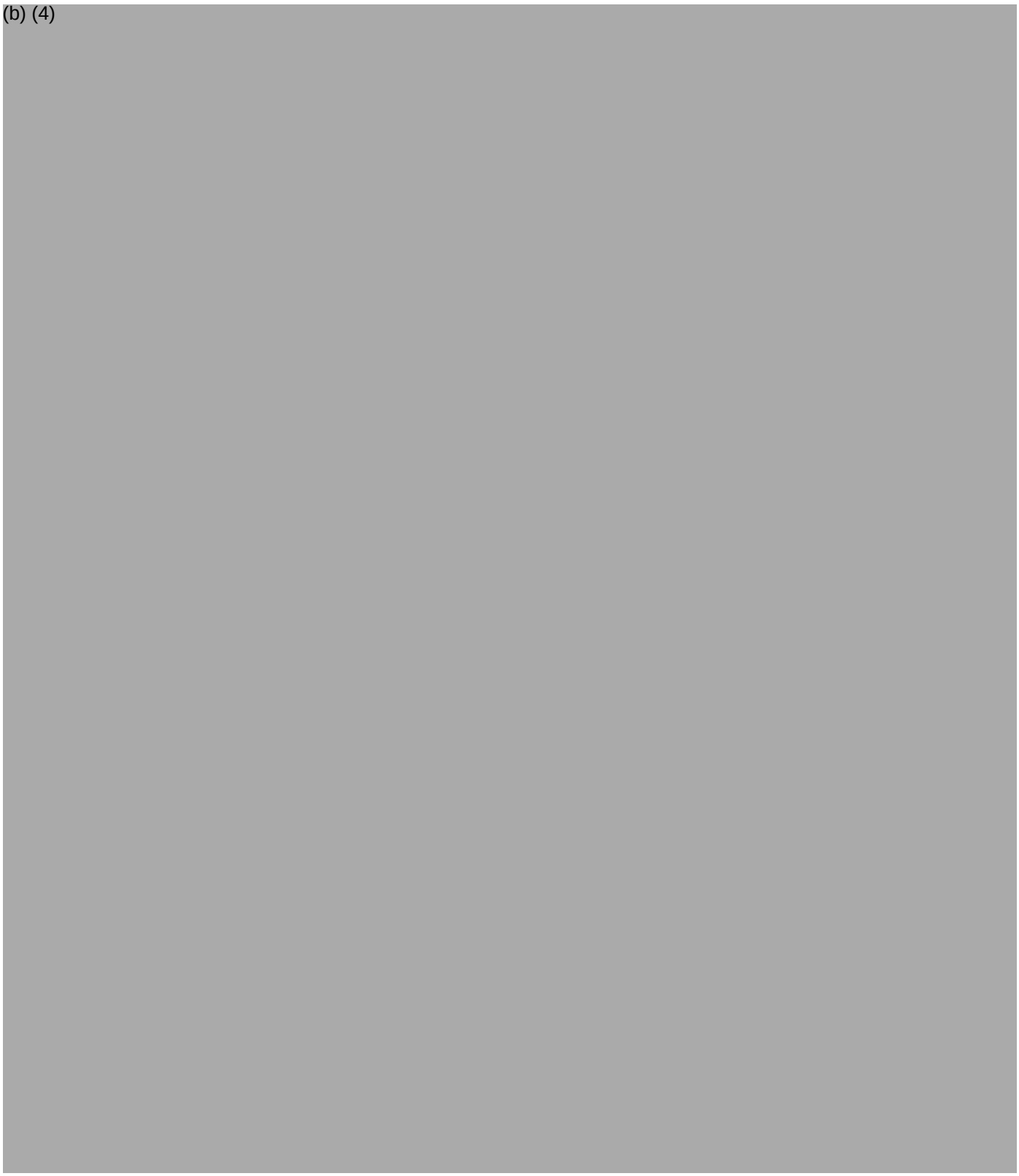
(b) (4)

(b) (4)

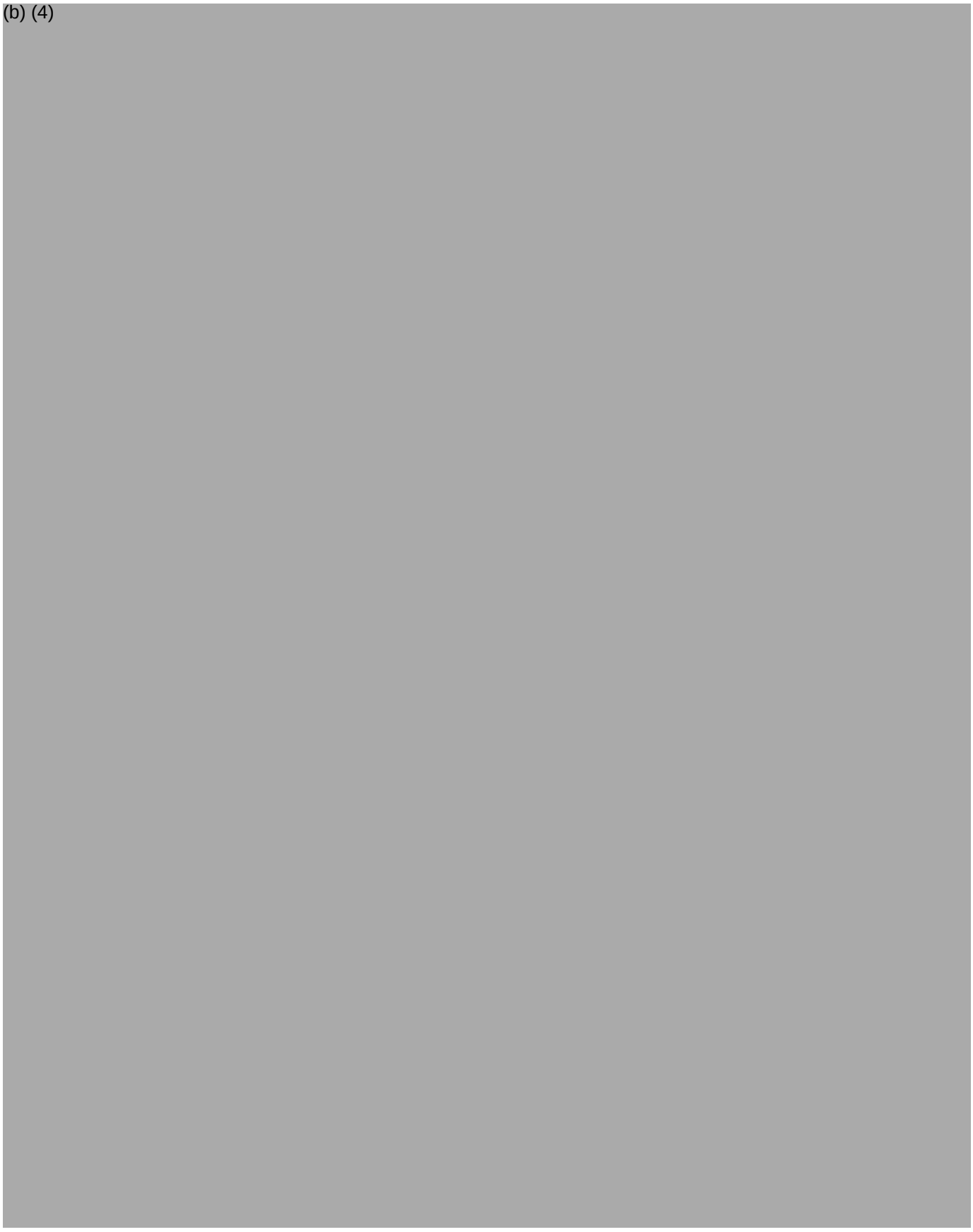
LUMENIS®

(b) (4)

[redacted]



(b) (4)



(b) (4)

Sincerely,

Yoram levy
yoram@qsitemed.com
(972)4-638-8837 Cell (972)52-279-2871
Fax (972)4-638-0510

LUMENIS®

Attachment Table of Contents

Attachment No. 1: (b) (4) Waveguide Data Sheet 8

Attachment No. 2: ANSI/AAMI/ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat Standards Data Report Form (FDA 3654) 9

LUMENIS®

Attachment No. 1: (b) (4) Waveguide Data Sheet

Attachment No. 2: ANSI/AAMI/ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat Standards Data Report Form (FDA 3654)

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

AANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 0214-261		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AANSI/AAMI/ISO 17665-1:2006 STERILIZATION OF HEALTH CARE PRODUCTS - MOIST HEAT - PART 1 REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	N/A There were no deviations or alternate test options used	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED□		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED□		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED□		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

□ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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 control number.

From: Tan, Xin
Sent: Friday, April 05, 2013 5:57 PM
To: k130164@docs.fda.gov
Subject: Email Exchange_Additional Information and Response to Deficiencies

From: Yoram Levy [mailto:yoram@qsitemed.com]
Sent: Sunday, March 03, 2013 12:37 PM
To: Tan, Xin
Cc: Ogden, Neil
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Dear Dr. Xin Tan,

We responded to your request for additional information in the attached files.
The attachments (include the form that was submitted again) are part of the "K130164 FiberLase Endure CO2 Fiber 510(k) Response".

Please email or call for any additional information that you may need for this 510k.

Best Regards,

Yoram
Yoram Levy, Qsite
qsite headerN
Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

From: Tan, Xin [mailto:Xin.Tan@fda.hhs.gov]
Sent: Tuesday, February 26, 2013 10:36 PM
To: 'Yoram Levy'
Cc: Ogden, Neil
Subject: Your 510(k) Submission K130164: Additional Information Required

Yoram,

We have reviewed your 510(k) submission K130164 to market the device – FiberLase Endure CO2 Fiber. We cannot determine if the device is substantially equivalent to your legally marketed predicate device (FiberLase CO2 Laser WaveGuide) based solely on the information you provided. To complete the review of your submission, we require the following information:

Performance Testing

(b) (4) [redacted]

(b) (4)

(b) (4)

Please submit your full response to the above deficiencies via email at your earliest convenience. Let me know if you have any questions regarding the content of this email.

Sincerely,

Sofia

XIN TAN, Ph.D. PHYSICIST
U.S. Food and Drug Administration
CDRH/OSEL/DP
10903 New Hampshire Avenue
White Oak Building 62, Room 1110
Silver Spring, Maryland 20993-0002
Phone: 301-796-2719
Fax: 301-796-9927
Email: xin.tan@fda.hhs.gov

From: Yoram Levy [mailto:yoram@qsitemed.com]
Sent: Monday, March 11, 2013 8:55 PM
To: Tan, Xin
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Yes we did.
(b) (4)

Best Regards,

Yoram
Yoram Levy, Qsite
qsite headerN

Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

From: Tan, Xin [mailto:Xin.Tan@fda.hhs.gov]
Sent: Monday, March 11, 2013 11:47 PM
To: 'Yoram Levy'
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Yoram,
(b) (4)

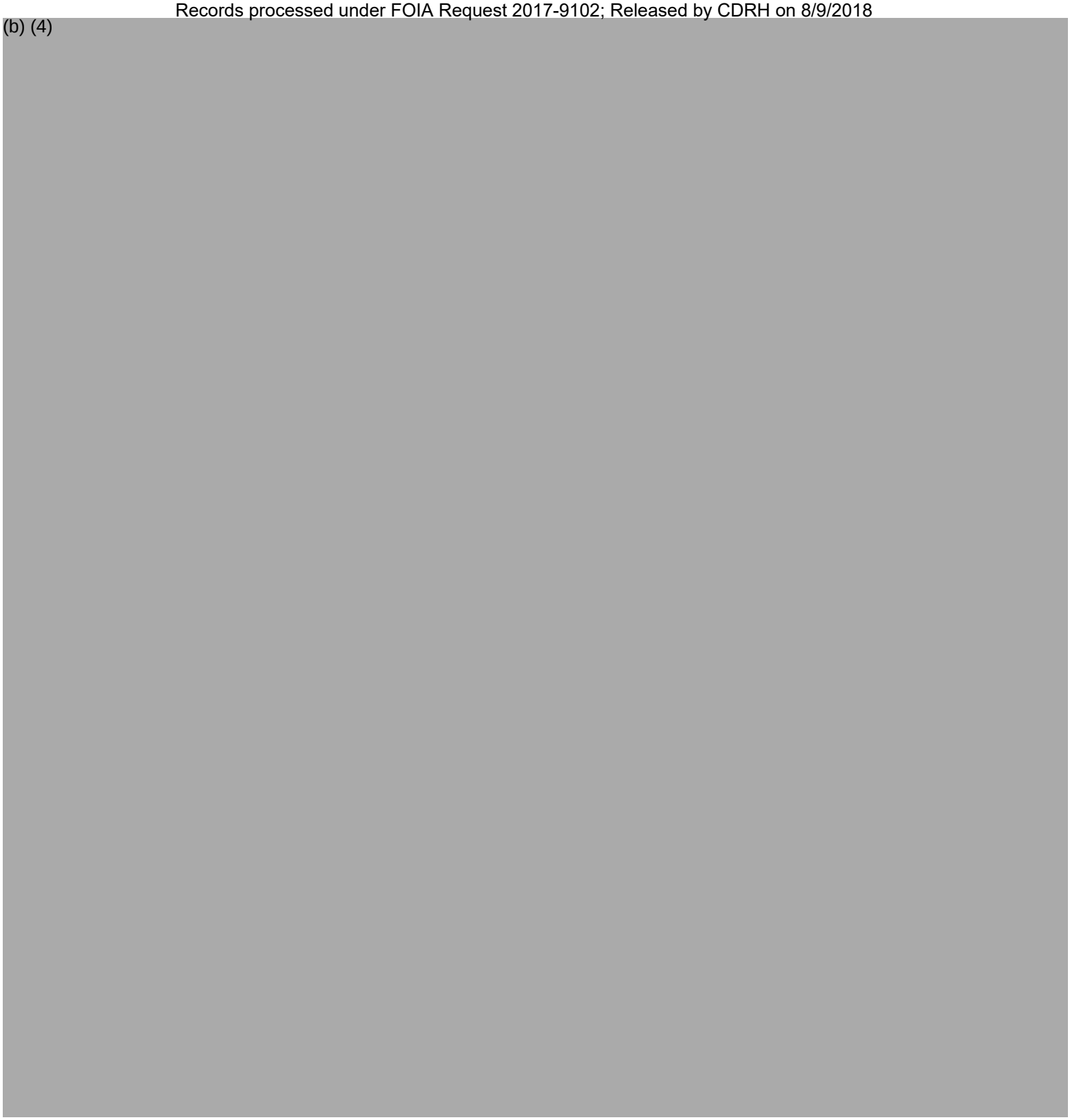
Sofia

From: Yoram Levy [mailto:yoram@qsitemed.com]
Sent: Monday, March 11, 2013 3:19 AM
To: Tan, Xin
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Dear Sofia,

(b) (4)

(b) (4)



(b) (4)

(b) (4)

Please email any farther questions that you have.

Best Regards,

Yoram Levy, Qsite
qsite headerN
Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

From: Tan, Xin [mailto:Xin.Tan@fda.hhs.gov]
Sent: Saturday, March 09, 2013 12:54 AM
To: 'Yoram Levy'
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Yoram,

(b) (4)

Sofia

From: Yoram Levy [mailto:yoram@qsitemed.com]
Sent: Friday, March 08, 2013 10:49 AM
To: Tan, Xin
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Dear Sofia,

(b) (4)

.

Best Regards,

Yoram Levy, Qsite
qsite headerN
Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

From: Tan, Xin [mailto:Xin.Tan@fda.hhs.gov]
Sent: Friday, March 08, 2013 1:08 AM
To: 'Yoram Levy'
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Yoram,

(b) (4)

Sofia

From: Yoram Levy [mailto:yoram@qsitemed.com]
Sent: Sunday, March 03, 2013 12:37 PM
To: Tan, Xin
Cc: Ogden, Neil
Subject: RE: Your 510(k) Submission K130164: Additional Information Required

Dear Dr. Xin Tan,

(b) (4)

.

Best Regards,

Yoram Levy, Qsite
qsite headerN
Tel (972)4-638-8837, Fax (972)4-638-0510
Cell (972)52-279-2871

From: Tan, Xin [mailto:Xin.Tan@fda.hhs.gov]
Sent: Tuesday, February 26, 2013 10:36 PM
To: 'Yoram Levy'
Cc: Ogden, Neil
Subject: Your 510(k) Submission K130164: Additional Information Required

Yoram,

(b) (4)

(b) (4) :

Performance Testing

(b) (4)

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(b) (4)

Please submit your full response to the above deficiencies via email at your earliest convenience. Let me know if you have any questions regarding the content of this email.

Sincerely,

Sofia

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