Section #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Prepared: 06/07/2013

OCT 18 2013

2. Sponsor

Beijing Honkon Technologies Co., Ltd.
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Establishment Registration Number: Not yet registered

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Multifunctional Series
Proposed Device Common Name: Intense Pulse Light (IPL)

Regulatory Information
Classification Name: powered laser surgical instrument
Classification: II;
Product Code: ONF;
Regulation Number: 21 CFR 878.4810;
Review Panel: General & Plastic Surgery;

Intended Use Statement:

The Multifunctional Series device (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in hair removal, moderate inflammatory acne vulgaris, and benign cutaneous vascular lesions.

Conditions	Filter setting and wavelength scope	Skin type				
		I	II	III	IV	V
Hair Removal		610-1200	610-1200	610-1200	610-1200	610-1200
Acne		530-1200	530-1200	530-1200	530-1200	530-1200
Vascular Lesions		585-1200	585-1200	585-1200	585-1200	585-1200

5. Predicate Device Identification

510(k) Number: K122995
Predicate Device Name: Intense Pulsed Light (IPL) Systems
Manufacturer: Beijing KES Biology Technology Co., Ltd.

510(k) Number: K093627
Predicate Device Name: IPULSELIGHT IPL SYSTEM
Manufacturer: Shanghai APOLO Medical Technology Co., Ltd

6. Device Description

The Multifunctional Series device are intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 530nm-1200nm. Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL Systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.

Based on this,The Multifunctional Series device (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in hair removal, acne, and blood vessel lesions.

The proposed device includes four models as Aeslight-S3D, HONKON-S3C, HONKON-M40e+ and HONKON-M80e+.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
b) IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
c) Performance Test (output energy, spot size)

8. Technological Characteristics Comparison

The proposed device has the same technological characteristics with the predicate device, such as light medium, wavelength, control method and intended use.

9. Substantially Equivalent Conclusion

Based on the comparison and analysis as following, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

Table III-1 General Comparison

ITEM	Proposed Device Multifunctional Series	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)	Remark
Product Code	ONF	ONF	ONF	SE
Regulation No	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Class	II	II	II	SE
Intended Use	The Multifunctional Series device (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in hair removal, moderate inflammatory acne vulgaris, and benign cutaneous vascular lesions.	The Intense Pulsed Light (IPL) Systems (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides (freckles), and vascular lesions.	IPulseLight IPL System (**HS 300C, HS 650**) are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions: Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen. Treatment of: - Moderate inflammatory acne vulgaris - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles). - Cutaneous lesions including scars - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins, spider anglomas and venous malformations. The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after light treatment in general aesthetic dermatologic and plastic surgery procedures. - Reduce pain during light treatment (via partial anesthesia from cooling) - Reduce discomfort during and/or associated with light treatment - Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper - and/or hypo pigmentation - Allow the use of higher light or laser fluencies for light treatments (such as for hair removal and the treatment of vascular or pigmented lesions) - Reduce potential side effects of light treatments (such as for hair removal and the treatment of vascular or pigmented lesions)	SE

Table III-2 Performance Comparison of model Aeslight-S3D

ITEM	Proposed Device Multifunctional Series (Aeslight-S3D)	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)	Remark
Light source	Intense pulsed light	Intense pulsed light	Intense pulsed light	SE
Wavelength	610-1200nm, 585-1200nm, 530-1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	420nm-1200, 510-1200nm, 560-1200nm, 610-1200nm, 640-1200nm (Standard); 480nm-1200, 585-1200nm, 690-1200nm, 755-1200nm (Options)	Analysis 1
Deliver system	Sapphire	Sapphire	Sapphire	SE
Energy Range	20-50J/cm²	10-60J/cm²	10-60J/cm²	Analysis 2
Pulse Delay	0.1-40ms	5 - 50ms	5 - 50ms	Analysis 3
Pulse Duration	1-25 ms	1-20 ms	2-20 ms	Analysis 4
Max. Power	2000 W	2000 W	1200 W	SE
Spot size	8mm*40mm, 15mm*60mm	MED-210: 15mmX50mm (optional: 12mmX33mm, 15mmX35mm) MED-230: A: 12mm X33mm; B: 15mmX50mm (optional: 15mmX35mm)	12x35mm, 15x50mm (Standard); 12x12mm, 12x25mm, 12x50mm, 15x35mm, 15x45mm (Options)	Analysis 5
Setting for Specified Indication for use:Hair Removal				
Wavelength (nm)	610-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-44	10-46	
Pulse Duration (ms)	3-15 ms	3-14	4-15	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X 33mm; 15mm X 50mm; 15mm X 35mm	12mm X 25mm; 12mm X 35mm; 12mm X 50mm; 15mm X 45mm	
Setting for Specified Indication for use:Acne				
Wavelength (nm)	530-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range	20-50	10-40	10-42	

(J/cm2)				
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	
Setting for Specified Indication for use:vascular lesions				
Wavelength (nm)	585-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-42	10-44	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	

Table III-3 Performance Comparison of model HONKON-S3C

ITEM	Proposed Device Multifunctional Series (HONKON-S3C)	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)	Remark
Light source	Intense pulsed light	Intense pulsed light	Intense pulsed light	SE
Wavelength	610-1200nm, 585-1200nm, 530-1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	420nm-1200, 510-1200nm, 560-1200nm, 610-1200nm, 640-1200nm (Standard); 480nm-1200, 585-1200nm, 690-1200nm, 755-1200nm (Options)	Analysis 1
Deliver system	Sapphire	Sapphire	Sapphire	SE
Energy Range	20-50J/cm²	10-60J/cm²	10-60J/cm²	Analysis 2
Pulse Delay	0.1-40ms	5 - 50ms	5 - 50ms	Analysis 3
Pulse Duration	1-25 ms	1-20 ms	2-20 ms	Analysis 4
Max. Power	2000 W	2000 W	1200 W	SE
Spot size	8mm*40mm, 15mm*60mm	MED-210: 15mmX50mm (optional: 12mmX33mm,	12x35mm, 15x50mm (Standard); 12x12mm, 12x25mm, 12x50mm,	Analysis 5

		15mmX35mm) MED-230: A: 12mm X33mm; B: 15mmX50mm (optional: 15mmX35mm)	15x35mm, 15x45mm (Options)	
Setting for Specified Indication for use:Hair Removal				
Wavelength (nm)	610-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-44	10-46	
Pulse Duration (ms)	3-15 ms	3-14	4-15	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X 33mm; 15mm X 50mm; 15mm X 35mm	12mm X 25mm; 12mm X 35mm; 12mm X 50mm; 15mm X 45mm	
Setting for Specified Indication for use:Acne				
Wavelength (nm)	530-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-40	10-42	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	
Setting for Specified Indication for use:vascular lesions				
Wavelength (nm)	585-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-42	10-44	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	

Table III-4 Performance Comparison of model HONKON-M40e+

ITEM	Proposed Device Multifunctional Series (HONKON-M40e+)	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)	Remark
Light source	Intense pulsed light	Intense pulsed light	Intense pulsed light	SE
Wavelength	610-1200nm, 585-1200nm, 530-1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	420nm-1200, 510-1200nm, 560-1200nm, 610-1200nm, 640-1200nm (Standard); 480nm-1200, 585-1200nm, 690-1200nm, 755-1200nm (Options)	Analysis 1
Deliver system	Sapphire	Sapphire	Sapphire	SE
Energy Range	20-50J/cm²	10-60J/cm²	10-60J/cm²	Analysis 2
Pulse Delay	0.1-40ms	5 - 50ms	5 - 50ms	Analysis 3
Pulse Duration	1-25 ms	1-20 ms	2-20 ms	Analysis 4
Max. Power	1250 W	2000 W	1200 W	Analysis 7
Spot size	8mm*40mm, 15mm*60mm	MED-210: 15mmX50mm (optional: 12mmX33mm, 15mmX35mm) MED-230: A: 12mm X33mm; B: 15mmX50mm (optional: 15mmX35mm)	12x35mm, 15x50mm (Standard); 12x12mm, 12x25mm, 12x50mm, 15x35mm, 15x45mm (Options)	Analysis 5
Setting for Specified Indication for use:Hair Removal				
Wavelength (nm)	610-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-44	10-46	
Pulse Duration (ms)	3-15 ms	3-14	4-15	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X 33mm; 15mm X 50mm; 15mm X 35mm	12mm X 25mm; 12mm X 35mm; 12mm X 50mm; 15mm X 45mm	
Setting for Specified Indication for use:Acne				
Wavelength (nm)	530-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6

Energy Range (J/cm2)	20-50	10-40	10-42	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	
Setting for Specified Indication for use:vascular lesions				
Wavelength (nm)	585-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	
Energy Range (J/cm2)	20-50	10-42	10-44	
Pulse Duration (ms)	3-10	3-8	3-9	Analysis 6
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	

Table III-5 Performance Comparison of model HONKON-M80e+

ITEM	Proposed Device Multifunctional Series (HONKON-M80e+)	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)	Remark
Light source	Intense pulsed light	Intense pulsed light	Intense pulsed light	SE
Wavelength	610-1200nm, 585-1200nm, 530-1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	420nm-1200, 510-1200nm, 560-1200nm, 610-1200nm, 640-1200nm (Standard); 480nm-1200, 585-1200nm, 690-1200nm, 755-1200nm (Options)	Analysis 1
Deliver system	Sapphire	Sapphire	Sapphire	SE
Energy Range	20-50J/cm²	10-60J/cm²	10-60J/cm²	Analysis 2
Pulse Delay	0.1-40ms	5 - 50ms	5 - 50ms	Analysis 3
Pulse Duration	1-25 ms	1-20 ms	2-20 ms	Analysis 4
Max. Power	1250 W	2000 W	1200 W	Analysis 7
Spot size	8mm*40mm, 15mm*60mm	MED-210: 15mmX50mm	12x35mm, 15x50mm (Standard);	Analysis

		(optional: 12mmX33mm, 15mmX35mm) MED-230: A: 12mm X33mm; B: 15mmX50mm (optional: 15mmX35mm)	12x12mm, 12x25mm, 12x50mm, 15x35mm, 15x45mm (Options)	5
Setting for Specified Indication for use:Hair Removal				
Wavelength (nm)	610-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-44	10-46	
Pulse Duration (ms)	3-15	3-14	4-15	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X 33mm; 15mm X 50mm; 15mm X 35mm	12mm X 25mm; 12mm X 35mm; 12mm X 50mm; 15mm X 45mm	
Setting for Specified Indication for use:Acne				
Wavelength (nm)	530-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-40	10-42	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	
Setting for Specified Indication for use:vascular lesions				
Wavelength (nm)	585-1200	640-1200/690-1200/750-1200	610-1200/640-1200/690-1200	Analysis 6
Energy Range (J/cm2)	20-50	10-42	10-44	
Pulse Duration (ms)	3-10	3-8	3-9	
Pulse Delay (ms)	15-35	16-32	15-30	
Spot size	8mm X 40mm; 15mm X 60mm	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm	

Analysis 1:

The wavelength range of proposed devices is very closed to that of predicate devices, the slight difference is considered to have no effect on effectiveness and safe.

Analysis 2:

The energy density of proposed devices is covered by the range of predicate devices, which is considered to have no effect on effectiveness and safe.

Analysis 3:

The pulse delay of proposed devices is covered by the range of predicate devices, which is considered to have no effect on effectiveness and safe.

Analysis 4:

The pulse duration of proposed devices is covered by the range of predicate devices, which is considered to have no effect on effectiveness and safe.

Analysis 5:

The spot size range of proposed devices is very closed to that of predicate devices, the slight difference is considered to have no effect on effectiveness and safe.

Analysis 6:

The setting of specified IFU of proposed device is very similar to that of predicate device, the difference is very slight, and only in the boundary value of the setting range. Therefore, the slight difference is considered to have no effect on effectiveness and safe.

Analysis 7:

The max. Input power of proposed devices is different with the predicate devices, all proposed devices meet the requirements of IEC 60601-1, So such different is considered to have no effect on effectiveness and safe.

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

Beijing Honkon Technologies Company, Ltd.
% Ms. Diana Hong
Shanghai Midlink Consulting Company, Ltd.
P.O. Box 237-023
200030 Shanghai
China

October 18, 2013

Re: K131859
Trade/Device Name: Multifunctional Series
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: ONF
Dated: September 9, 2013
Received: September 19, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

Indication for Use Statement

510(k) Number:

Device Name: Aeslight-S3D, HONKON-S3C, HONKON-M40e+ and HONKON-M80e+.

Indications for Use:

The Multifunctional Series device (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in hair removal, moderate inflammatory acne vulgaris, and benign cutaneous vascular lesions.

Conditions	Filter setting and wavelength scope	Skin type				
		I	II	III	IV	V
Hair Removal		610-1200	610-1200	610-1200	610-1200	610-1200
Acne		530-1200	530-1200	530-1200	530-1200	530-1200
Vascular Lesions		585-1200	585-1200	585-1200	585-1200	585-1200

☒ PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐ OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.10.18 12:04:12 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131859