From: eadministrator@tga.gov.au
To: s22 @qrbconsulting.com.au
Subject: Notification of entry on the ARTG for Product "Surgical/dermatological Er:YAG laser system" Application Id.DV-2014-DA-14529-1 [SEC=UNCLASSIFIED]
Date: Thursday, 11 September 2014 1:05:29 PM

Dear Client

ARTG Entry details:

ARTG No: 227865
Product Name: Surgical/dermatological Er:YAG laser system
Sponsor Name: Advanced Cosmeceuticals
Sponsor's own reference: Action surgical/dermatological laser system
Entry Type: Included
Date of Entry: 11/09/2014

I am writing to advise that your application to include the above mentioned device on the Australian Register of Therapeutic Goods (ARTG) was successful.
This e-mail is your confirmation of the approval of your application – you will not receive a further notification from the TGA by letter.
The device has been included on the ARTG, subject to the conditions stated on the ARTG Certificate. This certificate may be downloaded and printed by the Sponsor (or their agent) by logging in to the TGA eBusiness Services (eBS) website <www.ebs.tga.gov.au>.
The TGA will not be issuing a hard-copy of this certificate.
Reasons for the decision
The decision to include these medical devices on the ARTG was based on the information provided in the application, and your declaration that the matters certified in the application under section 41FD of the Act are complete and correct.
The next steps
The TGA Finance Services Group will issue an invoice for annual charges The inclusion of these devices commenced on the date specified in the ARTG Certificate. The continued inclusion on the ARTG is subject to payment of annual charges, and on compliance with the conditions placed on the inclusion.*
Ongoing monitoring of quality, safety and performance
Medical devices on the ARTG are subject to ongoing monitoring of their quality, safety and performance. These medical devices may be chosen, at any time as part of a random product review, to verify the matters certified under section 41FD of the Act, or may be subjected to a targeted product review if there are any potential or real risks identified with the use of the device.
Sponsors' ongoing regulatory responsibilities
Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market
These responsibilities include but are not limited to:
· Ensuring that any documentation relating to the medical device, or sample of the medical device, can be provided to the TGA upon request, and within the specified timeframes;
· Ensuring the advertising of the medical devices comply with the advertising requirements specified under Chapter 5 of the Act, and is consistent with the intended purpose for the device as certified under section 41FD. Advertising direct to consumers (other than healthcare professionals) must also comply with the Therapeutic Goods Advertising Code. A copy of this code can be found on the Therapeutic Goods Advertising Code Council website at <http://www.tgacc.com.au>. It is important to note that any advertising material submitted during the pre-market assessment is not assessed for compliance with the advertising requirements. The advertising material is only used to assist with clarifying the manufacturer's intended purpose for the device;
· Ensuring that any serious problem or adverse event associated with the use of the device is reported to the TGA within the timeframes specified under section 41MP of the Act. Further guidance regarding the obligations to report adverse events is available in Section 22 of the current version of the Australian Regulatory Guidelines for Medical Devices (ARGMD) on the TGA website http://www.tga.gov.au/industry/devices-argmd.htm ; and
· Ensuring that any recall of the device is undertaken in accordance with the Uniform Recall

Procedure for Therapeutic Goods and is coordinated by the Recalls Unit of the TGA. A copy of the recall procedure is available on the TGA website at http://www.tga.gov.au/industry/recalls-urptg.htm .

*Please note that under current transition provisions for in-vitro diagnostic (IVD) medical devices only, annual changes for ARTG entries for these products are set at $0 to 30 June 2017.

This is an automatic email please do not reply.

Work Management

Task - Application Without Audit - Assessment

Work Process ID:	DA-2014-05980-1	Work Process Status:	Completed
Work Process Manager:	Class IIb - Approved	Assigned To:	s22
Default TRIM Container ID:			

Task Description

For Manufacturers Evidence check:
- appropriate Conformity Assessment Procedure for class of device
- scope covers the devices
- date issued and expiry date
- issuing body (TGA or EU Notified Body)

For Device Application Form check:
- eligibility for inclusion (i.e. it is a medical device, not an excluded good)
- animal origin, medicine, microbial origin
- device correctly classified
- suitable GMDN code and term
- appropriate intended purpose
- answers to specific questions (e.g. is it active, is it invasive etc)

If application is effective:
Record an "approved" decision and complete this task before proceeding to the notification task.

If application is not effective:
Using the s41JA request letter template, inform the sponsor to rectify any deficiencies as appropriate (add Device Return To Applicant Task).
Limit to one request for information (including push back).
If application is still deemed ineffective, record a "rejected" decision and enter a reason on the device application and/or this task.
Complete this task and proceed to the notification task.

Task Information

Task Information

Work Process Component:	Assessment		
Task Status:	Completed		
Planned Start:	09/09/2014	Planned End:	22/09/2014
Actual Start:	11/09/2014	Actual End:	11/09/2014
Management Comment:			
Checklist:	☒ Check Manufacturers Evidence ☒ Check Application Form Details ☒ Record Decision		
Checklist Comments:			
Outcome:	complete		

Task Specifics

Delegate:	s22

Decision Date: 11/09/2014

Application	Current Decision	Reason
DeviceApplication DV-2014-DA-14529-1	Approved	N/A

Work Process Summary

Clock Information

Clock Information

View Stop Clocks

Task Clock Status	Stopped		
Elapsed TGA Days:	7	Remaining TGA Days:	0

Supporting Information

Letter History :

Attached Document History :

No Task Related Documents

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 89674-2010-CE-KOR-NA Rev. 7.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Lutronic Corporation

Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

for design, production and final product inspection/testing of

Medical lasers, Phototherapy Unit, and Intense Pulsed Light Electrosurgical Unit

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 15 November 2013

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

s22 [redacted]

s22 [redacted]
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
21 December 2015

s22 [redacted]
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

DET NORSKE VERITAS * 1864 *

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate 2006-OSL-MDD-0424	2005-12-21
	Recertification	2010-12-21
1.0	Scope extension- New Products and model added	2011-04-27
2.0	Scope extension- New product group added (Electrosurgical unit)	2011-11-30
3.0	Scope extension- New product group added (Pulsed diode laser)	2012-04-22
4.0	Scope extension- New product group added (CLARITY™)	2012-06-06
5.0	Scope extension- New product group added (ACTION II) & EU Rep changed	2012-12-04
6.0	Site relocation and Scope change (products withdrawal)	2013-04-23
7.0	**Scope extension- New product group added (AM10)**	**2013-11-15**

Products covered by this Certificate

Product Description	Product	Class
Pulsed Er-YAG Laser	ACTION II	IIb
Pulsed Nd-YAG Laser	ACCUSCULPT II Accessory : Optical Fiber, Cannula, Handpiece	IIb
Frequency Doubled Q-switched Nd-YAG Laser	Spectra VRM III SPECTRA	IIb
Surgical CO_2 Laser (Tube Type)	SP II, DENTA II	IIb
Surgical CO_2 Laser (RF Type)	eCO2, eCO2 Plus	IIb
Er-GLASS Fiber Laser	MOSAIC HP	IIb
Pulsed Diode Laser	ADVANTAGE Handpiece: D1-800/D3-800	IIb
Alexandrite+Long-pulsed Nd:YAG Laser/ Long-pulsed Nd:YAG Laser/ Alexandrite Laser	CLARITY ™ LPC CLARITY ™ LPY CLARITY ™ LPA	IIb
Phototherapy Unit	HEALITE II	IIb
Intense Pulsed Light	SOLARI	IIb

Electrosurgical unit	INFINI Disposable accessories; MFR Tip and SFR Tip	IIb
Ophthalmic Nd:YLF Laser	**AM10**	**IIb**

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Lutronic Corporation	Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

EU Representative:

Obelis s.a., Bd. Général Wahis 53, 1030 Brussels, BELGIUM

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 89674-2010-CE-KOR-NA Rev. 8.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Lutronic Corporation

Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

for design, production and final product inspection/testing of

Medical lasers, Phototherapy Unit, and Intense Pulsed Light Electrosurgical Unit

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 30 May 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

s22 [redacted]

s22 [redacted]
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
21 December 2015

s22 [redacted]
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

DET NORSKE VERITAS * 1864 *

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

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3.0	Scope extension- New product group added (Pulsed diode laser)	2012-04-22
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5.0	Scope extension- New product group added (ACTION II) & EU Rep changed	2012-12-04
6.0	Site relocation and Scope change (products withdrawal)	2013-04-23
7.0	Scope extension- New product group added (AM10)	2013-11-15
8.0	**Model add- ACTION II accessory and SPECTRA XT**	**2014-05-30**

Products covered by this Certificate

Product Description	Product	Class
Pulsed Er-YAG Laser	ACTION II **Handpiece:** Zoom,ShP,Fractional,**Petit**	IIb
Pulsed Nd-YAG Laser	ACCUSCULPT II Accessory : Optical Fiber, Cannula, Handpiece	IIb
Frequency Doubled Q-switched Nd-YAG Laser	Spectra VRM III SPECTRA **SPECTRA XT**	IIb
Surgical CO_2 Laser (Tube Type)	SP II, DENTA II	IIb
Surgical CO_2 Laser (RF Type)	eCO2, eCO2 Plus	IIb
Er-GLASS Fiber Laser	MOSAIC HP	IIb
Pulsed Diode Laser	ADVANTAGE Handpiece: D1-800/D3-800	IIb
Alexandrite+Long-pulsed Nd:YAG Laser/ Long-pulsed Nd:YAG Laser/ Alexandrite Laser	CLARITY ™ LPC CLARITY ™ LPY CLARITY ™ LPA	IIb
Phototherapy Unit	HEALITE II	IIb

Intense Pulsed Light	SOLARI	IIb
Electrosurgical unit	INFINI Disposable accessories; MFR Tip and SFR Tip	IIb
Ophthalmic Nd:YLF Laser	AM10	IIb

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Lutronic Corporation	Lutronic Center, 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Korea

EU Representative:

Obelis s.a., Bd. Général Wahis 53, 1030 Brussels, BELGIUM

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
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- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

Medical Device Application

Class IIb
Status: Approved

Application Change history

Application Progress Date	
Date received:	27/08/2014
Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID:	227865
Product ID:	433023

Application Details	
Application identifier:	DV-2014-DA-14529-1
Submission identifier:	DA-2014-05980-1
Sponsor's own reference:	Action surgical/dermatological laser system
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ● No
Will you be applying for listing of this product on the Prosthesis List?	○ Yes ● No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	○ Yes ● No
Cancel ARTG - product:	
Is this application supported by EU MDR/IVDR certification?	

Sponsor Details	
Agent name:	QRB & Associates Pty Ltd t/a QRB Consulting

Sponsor name:	Advanced Cosmeceuticals
Contact details:	s22 [redacted]
Contact email:	s22 [redacted]@qrbconsulting.com.au

Class Details	
This application is to:	
Class:	Class IIb

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:	No
Sterilisation Method:	
Is the device intended to be invasive:	Yes
s the device, or any form of the device, intended for single use:	No
Is the device an active device:	Yes
Does the device contain material or ingredients of microbial origin:	No
Does the device contain material or ingredients of recombinant origin:	No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	No
Does the device contain material or ingredients of Human Origin:	No
Does the device contain Human Blood or its components:	
Does the device consist of:	Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable	No
Animal Species:	
Country of Origin:	
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:	
Is the device medicated:	No
Is the device formulated:	
Does the product contain a medicine that is supplied separately in the Australian Market:	No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:	No
Does the device contain a metal on metal bearing:	
I declare that this device contains only components that are medical devices which have been individually certified.	No
Is this a Class IIb spinal fusion device:	
Is the device software:	

Manufacturer Details	
Manufacturer evidence number:	DV-2014-MC-03965-1 :manufacturer evidence - Lutronic Corp v1
Manufacturer name:	Lutronic Corporation (Korea - Republic of)[50372]
Manufacturer address as on evidence:	Lutronic Center 219 Sowon-ro Deogyang-si Goyang-si Gyeonggi-do Korea - Republic of S [201745]

GMDNS Code and Description	
GMDNS code and description:	Surgical/dermatological Er:YAG laser system[47884]

Device Category Terms	
Device category 1:	
Device category 2:	
Device category 3:	

Product Details	
Unique Product Identifier (UPI):	
Total number of devices covered:	
Functional description:	

Variant List		
#	Variant type	Variant range

Standard Conditions
- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information. - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Non Standard Conditions	
Note: A non standard conditions must not contain semi colons.	
	To remove, enter item #

Declaration

(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition

of a medical device; and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) I:
(i) have available sufficient information to substantiate that compliance with the essential principles; or
(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
(g) I:
(i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
(j) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:
A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:
.....

History

11/09/2014 1:05:29 PM Approved.

Review Completed - Accepted, 11/09/2014)

Record		Date	
Fee	940	Date Paid	03/09/2014
		Date Decision	11/09/2014

Start Dates		Finish Dates		Working Days
Application Received	27/08/2014	Payment Received	03/09/2014	5
Payment Received	03/09/2014	Application Decision	11/09/2014	11
			Total Working Days	16

Medical Device Application

ARTG No : 227865

Class IIb
Status: Approved

Application Change history

Application Progress Date	
Date received:	27/08/2014

Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: No
Is the device intended to be invasive: Yes
Is the device, or any form of the device, intended for single use: No
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Does the product contain a medicine that is supplied separately in the Australian Market: No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Application Summary

Application ID:	DV-2014-DA-14529-1
Submission ID:	DA-2014-05980-1
Sponsor's own reference:	Action surgical/dermatological laser system
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ● No
Will you be applying for listing of this product on the Prosthesis List?	○ Yes ● No
Will you be applying for listing of this product on the	○ Yes ● No

Co-dependent or hybrid technology application list?	
Sponsor name:	Advanced Cosmeceuticals
Sponsor ID:	22051
Agent name:	QRB & Associates Pty Ltd t/a QRB Consulting
Contact details:	s22 [redacted]
Contact email:	s22 [redacted]@qrbconsulting.com.au
Is this application supported by EU MDR/IVDR certification?	

Manufacturer Information	
Manufacturer's evidence:	DV-2014-MC-03965-1 :manufacturer evidence - Lutronic Corp v1 Goto
Manufacturer name:	Lutronic Corporation (Korea - Republic of)[50372]
Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Assessment body:	Det Norske Veritas Certification AS [0434]
GMDN code:	Surgical/dermatological Er:YAG laser system[47884]
GMDN description:	A mains electricity (AC-powered) Light Amplification by Stimulated Emission of Radiation (LASER) device assembly in which input energy is used to excite a rod of yttrium-aluminium-garnet (YAG) crystal doped with erbium (Er) as the active medium to emit a beam of intense, coherent, monochromatic electromagnetic (EM) radiation for application in a wide range of surgical/dermatological procedures. It includes a light source, delivery/positioning device(s), and controls/foot-switch and is intended to incise, excise vaporize, ablate, and coagulate soft/cartilaginous tissue. Its high-water affinity and high-fluency pulses produce a narrow zone of damage around the tissue vaporization crater.
Intended purpose:	The ACTION II laser system is an Er:YAG laser producing a pulsed beam of coherent infrared light for application in a wide range of surgical/dermatological procedures, including scar revision, epidermal benign disorder, epidermal pigment lesions, stress urinary incontinence and vaginal relaxation syndrome.

Device Category Terms

Attached Documentation

History

11/09/2014 1:05:29 PM Approved.

Review Completed - Accepted, 11/09/2014)

Record		Date	
Fee:	940	Date Paid:	03/09/2014
		Date Decision:	11/09/2014

Start Dates		Finish Dates		Working Days
Application Received	27/08/2014	Payment Received	03/09/2014	5
Payment Received	03/09/2014	Application Decision	11/09/2014	11
			Total Working Days	16