

## **TÀI LIỆU THỪA NHẬN KẾT QUẢ PHÂN LOẠI**

Tên Sản Phẩm: Hệ thống dụng cụ đặt thủy tinh thể Unfolder (các loại, các cỡ)

Chủng Loại (Model): Silvert, EmeraldT, EmeraldXL, Emerald-AR, Dk7796

Chủ sở hữu: Johnson & Johnson Surgical Vision, Inc. (AMO)

Hãng sản xuất: RMS Co., USA; Duckworth & Kent LTD., UK

Phân loại tại FDA bởi USA và UK: Loại I

Quy đổi phân loại tại Việt Nam: LOẠI A

**Nhấp chuột vào đường link sau:**

Link FDA online: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?ID=4154>

Kết quả như sau:

U.S. Department of Health & Human Services

U.S. FOOD & DRUG ADMINISTRATION

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## Product Classification

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Device	Lens, Guide, Intraocular
Regulation Description	Intraocular lens guide.
Regulation Medical Specialty	Ophthalmic
Review Panel	Ophthalmic
Product Code	KYB
Premarket Review	<a href="#">Office of Device Evaluation (ODE)</a> Division of <a href="#">Ophthalmic and Ear, Nose and Throat Devices (DOED)</a> Intraocular and Corneal Implants Devices Branch (ICIB)
Submission Type	510(K) Exempt
Regulation Number	886.4300
Device Class	1
Total Product Life Cycle (TPLC)	<a href="#">TPLC Product Code Report</a>
GMP Exempt?	No

**Note:** FDA has exempted almost all class I devices (with the exception of [reserved devices](#)) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the [Device Registration and Listing website](#) for additional information.

**Recognized Consensus Standard**  
[10-78 ISO 11979-3](#) Third edition 2012-12-01  
[Ophthalmic implants - Intraocular lenses -- Part 3: Mechanical properties and test methods](#)

Implanted Device? No  
Life-Sustain/Support Device? No

**Third Party Review**

- Eligible for [Accredited Persons Program](#)

**Accredited Persons**

- [Center For Measurement Standards Of Industrial](#)
- [Third Party Review Group, Llc](#)
- [Tuv Sud America Inc.](#)

Page Last Updated: 06/26/2017  
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## DECLARATION OF CONFORMITY

to  
Directive 93/42/EEC concerning Medical Devices

Name of Product:	<b>Insertion System Class 1 Products</b>
Legal (labeled) Manufacturer Name: Manufacturer's Address:	Abbott Medical Optics Inc. 1700 E. St. Andrew Place Santa Ana, California 92705 USA
EU Representative:	AMO Ireland Block B Liffey Valley Office Campus Quarryvale, Co Dublin Ireland
Contract Manufacturer:	RMS 8600 Evergreen Blvd. N Minneapolis, MN 55433-6036 USA

We, the undersigned, hereby declare on our own responsibility that the medical devices listed on this Declaration of Conformity meet all the provisions of the Directive 93/42/EEC concerning medical devices (including all subsequent amendments), which apply to them.

### **Notified Body**

Not applicable, as Class I products (non sterile, no measuring function)

### **Conformity Assessment Procedure**

Annex VII, MDD/93/42/EEC

### **EC Certificate Number**

Not applicable, as Class I products

### **Product Family Name / Number:**

UNFOLDER Emerald Series Handpiece, Models Emerald-AR, EmeraldT, EmeraldXL, SilverT, PSHST

This document is valid from the day of signature.



*O Biggs*  
Ophelia Biggs  
Associate Director, Regulatory Affairs

Date March 16, 2017

*D Stefani*  
Dinamarie Stefani  
Director, Quality Assurance

Date March 16, 2017

NOTARIAL CERTIFICATE

BE IT KNOWN that I, Daniel St. John Whiddett, of Broadway Chambers, Letchworth Garden City, Hertfordshire SG6 3AD, United Kingdom, a duly authorised notary public, CERTIFY that the document annexed hereto is a certified copy of the Declaration of Conformity under the Medical Device Directive 93/42/EEC dated 23<sup>rd</sup> January 2017 produced to me by Josephine Grace Barker, Managing Director of Duckworth & Kent Limited.

IN WITNESS whereof I have signed my name and affixed my seal of office.

Signed and sealed at  
Broadway Chambers,  
Letchworth this 3<sup>rd</sup>  
Day of January 2017

  
.....  
NOTARY PUBLIC  
England and Wales  
Protocol No. 744 (1)





# Duckworth & Kent Ltd.

titanium surgical instrument manufacturer

ISO9001:2008 and ISO13485:2003 Certified

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Royston Road Baldock  
Herts SG7 6XL, England  
Telephone: +44 (0) 1462 893254  
Fax: +44 (0) 1462 896288  
Email: info@duckworth-and-kent.com  
Web: www.duckworth-and-kent.com

TO WHOM IT MAY CONCERN:

The instruments listed below are all classified as Class I under the Medical Device Directive 93/42/EEC. This means that they are self-regulated and therefore no external Notified Body Certificates are issued.

I have attached a copy of our original registration letter with our local Competent Authority (MHRA) which covers all of our Class I devices.

ITEM NAME	PRODUCT
VIPER II HANDPIECE	DK7786
ONE SERIES ULTRA FORCEPS	DK7726
ONE SERIES ULTRA HANDPIECE - SCREW-STYLE	DK7791
THE UNFOLDER PLATINUM 1 SERIES HANDPIES	DK7796

Signed:

J G Barker  
Managing Director  
DUCKWORTH & KENT LTD

Date:

23/11/2017

*at the Leading Edge*

Chairman: T. A. Waldoock  
Managing Director: J. Barker  
Directors: F. Waldoock  
A. Waldoock, B.Med.Sci. (Hons), B.M., B.S., F.R.C.Ophth., M.D.  
A. Waldoock, M.Eng.

Registered at the above address  
VAT No 196 5712 27  
Registration No 620074



guarding public health

MHRA

our Ref: CA000263

Martin Lock  
Duckworth And Kent Ltd  
Terence House  
7 Marquis Business Centre  
Royston Road, Baldock, Herts  
SG7 6XL  
United Kingdom

RECEIVED  
15 JUL 2009

03 July 2009

Dear Mr Lock,

**MEDICAL DEVICES REGULATIONS 2002: REGULATION 19**  
**Registration of Persons Placing General Medical Devices on the Market**

Thank you for informing the Competent Authority of your company's details and for supplying the medical device information in regards to the change to the original notification dated 09/02/96.

The change(s) to registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

**For Manufacturers of Class I medical devices, Assemblers, and Sterilisers**

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

**For Manufacturers of Custom-made devices**

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the bottom of this letter, which we ask you to quote in all future correspondence and communications.

**Please inform us of any changes to:**

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

**Class I Devices:**

*Surgical Instruments (Re-Usable And Non-Powered)*  
*Surgical Instrument Accessories*

**Custom Made Devices:**

*None*

**Products Covered By Article 12:**  
**None**

**Confidentiality**

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential. This will apply to all medical devices and in vitro diagnostic medical devices.

Should you have any queries regarding your registration please do not hesitate to contact us.

Yours sincerely

*Jasu Patel*

Jasu Patel

020 7084 3195  
020 7084 3112

Email: [Jasu.Patel@mhra.gsi.gov.uk](mailto:Jasu.Patel@mhra.gsi.gov.uk)



