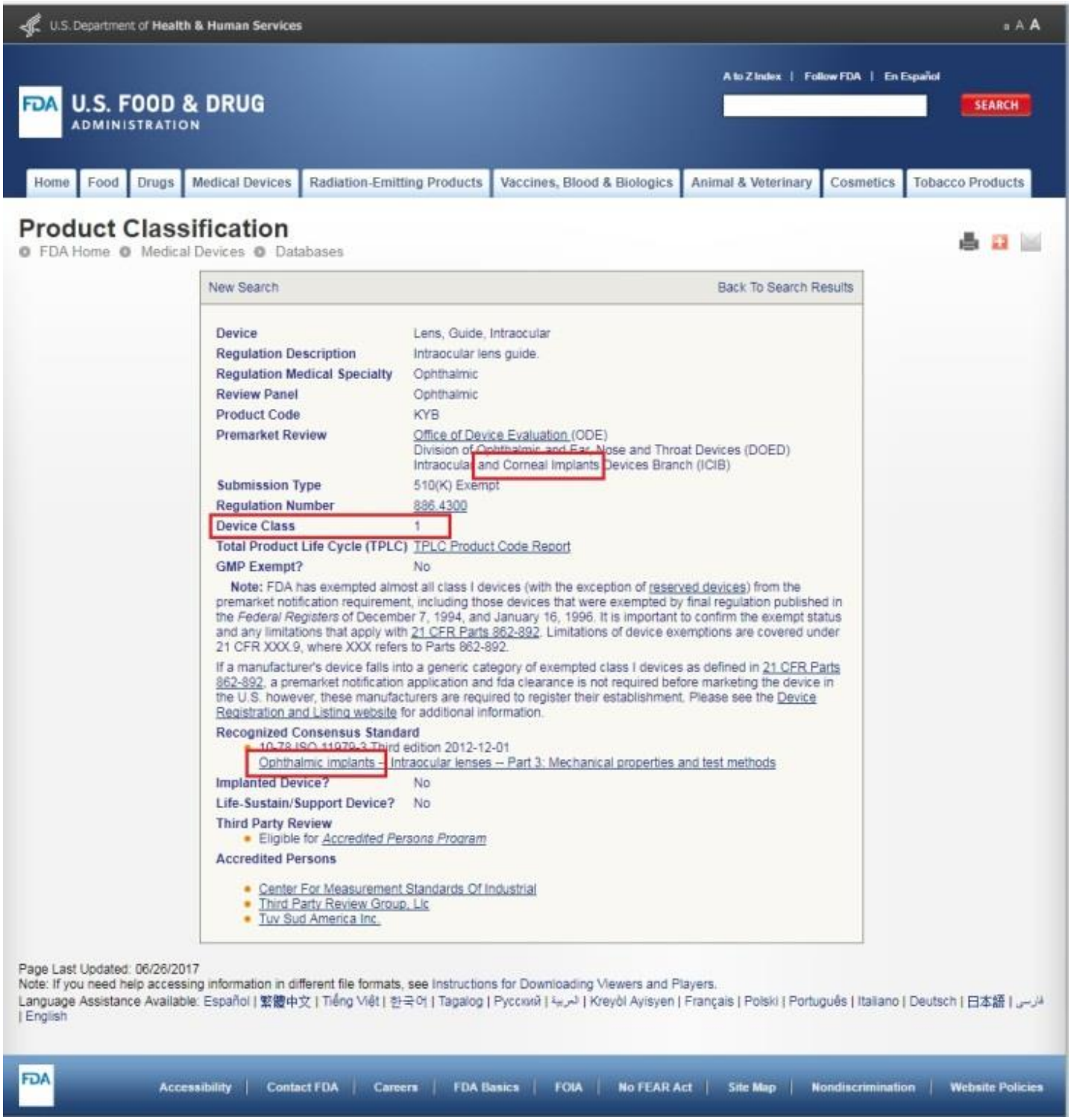
TÀI LIỆU THỪA NHẬN KẾT QUẢ PHÂN LOẠI

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/cfpcd/classification.cfm?ID=4154

Kết quả như sau:



1700 E. St. Andrew Place
Santa Ana, CA 92705 USA

Abbott
Medical Optics

DECLARATION OF CONFORMITY

to
Directive 93/42/EEC concerning Medical Devices

Name of Product:	**Insertion System Class 1 Products**
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.

1700 E. St. Andrew Place
Santa Ana, CA 92705 USA

Abbott
Medical Optics

OBiggs

Ophelia Biggs
Associate Director, Regulatory Affairs

Date March 16, 2017

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 23rd 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 31st
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

Terence House
7 Marquis Business Centre
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: JGBarker

J G Barker
Managing Director
DUCKWORTH & KENT LTD

Date: 23/1/2017

guarding public health

MHRA

ur Ref: CA000263

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

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