राजेन्द्र आयुर्विज्ञान संस्थान
(झारखण्ड सरकार का एक स्वयतशासी संस्थान)
राँची–834009 (झारखण्ड)
दुरभाष: 0651–2541533, फैक्स: 0651–2540629,
E-mail: rimsranchi@rediffmail.com

RAJENDRA INSTITUTE OF MEDICAL SCIENCES
(An Autonomous Institute under Govt. of Jharkhand)
Ranchi-834009 (Jharkhand)
Phone: 0651-2541533, Fax: 0651-2540629,
Email : rimsranchi@rediffmail.com

Notice no. RIMS/(ME4) ..4378..... Dated ..16/12/23

SUBJECT : PURCHASE OF ENDO VASCULAR RADIOFREQUENCY SYSTEM (RFA), MAKE – F CARE SYSTEM, MODAL – EVRF – MedRF4000 FOR DEPARTMENT OF CTVS AND GENERAL SURGERY RIMS, RANCHI ON PROPRIETARY BASIS.

The RIMS, Ranchi is going to purchase of **Endo Vascular Radiofrequency System (RFA), Make – F Care system, Modal – EVRF – MedRF4000** The joint proposal submitted by M/s F Care system and M/s NovoMed Incorporation Pvt. Ltd., Mumbai is attached & uploaded on website.

The above documents are being uploaded for open Information to submit objections, comments, if any from any manufacturer regarding proprietary nature of the equipment / item within 21 days from the date of issue / uploading of the notification NS/97.

The comments should be sent to Director, Rajendra Institute of Medical Sciences, (RIMS) on or before 21 days from the issue of this notice upto 12:30 PM by registered post mentioning the subject on envelope or through GeM Portal, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on proprietary merits.

Encl.

1. Price Offer
2. PAC Certificate
3. Authorization Letter
4. Technical Specifications & Quotation

16/12/23

Director,
Rajendra Institute of Medical Sciences
Ranchi

30/11/2023

30/11/23

(43)

Proprietary Article Certificate in the ***following form*** is to be provided by the Ministry/Department before procuring the goods from a single source under the provision of sub Rule 166 (i) and 166 (iii) as applicable.

(i) The indented goods are manufactured by M/s Novo Med Incosporation Pv.t. Ltd.

(ii) No other make or model is acceptable for the following reasons : As per the Company declaration Endovascular Radiofrequency System in a Proprietory item and no other make is available currently. This may be uploaded to RIMS Webside to get objectes if any..

(iii) Concurrence of finance wing to the proposal vide: .....

(iv) Approval of the competent authority vide

Signature with date and
designation of Indenting Officer

(42)

Proprietary Article Certificate in the ***following form*** is to be provided by the Ministry/Department before procuring the goods from a single source under the provision of sub Rule 166 (i) and 166 (iii) as applicable.

(i) The indented goods are manufactured by M/s ..Nova Med Incorporation Pvt Ltd.

(ii) No other make or model is acceptable for the following reasons :..As per company declarate this is proprietary and no other make available. This may be uploaded to the RIMS website to get NOC in 21 days.

(iii) Concurrence of finance wing to the proposal vide: .....

(iv) Approval of the competent authority vide

25/9/22

Signature with date and

designation of Indenting Officer

Dr. VINEET MAHAJAN
MBBS,MS,M.Ch.,FIACS
Professor & Head
Cardiothoracic & Vascular Surgery
Rajendra Institute of Medical Sciences, Ranchi-834009

Prof. & H.O.D.
Surgery, RIMS
Ranchi

OFFICE OF DIRECTOR RIMS, RANCHI
Receiving Date: 19/11/22
DC-410

(18)

NOVOMED

NovoMed Incorporation Pvt. Ltd.

103, The Summit Business Bay, Prakashwadi, Near PVR Cinema, Village Gundavali,
Andheri Kurla Road, Andheri (East), Mumbai - 400093 Tel: 022 - 26844066 / 67 / 68
Email: info@novomed.in Website: www.novomed.in GSTIN No: 27AADCN5387P1ZN

25.10.2021

HOD, Surgery
25/11/22

To,
The Director
Rajendra Institute of Medical Science (RIMS)
Ranchi
Sub: Covering Letter

Endovenous Radiofrequency system is based on the principle of radiofrequency induced thermotherapy. The MedRF4000® is an all-in-one device for the treatment of all grades of haemorrhoids, fistulas and different kinds of varicose veins – from the very small spider veins and perforating veins to Great Saphenous Vein (GSV).

F care systems recently developed a probe for the treatment of fistulas with the same MedRF4000® device.

As this system does not require the hospitalization, it becomes very economical for the hospital to save money on hospital beds, admission and other services. It can be done by doing the local anaesthesia & no post –operative care is required.

More than 50 Units have been sold in India and we have received the great response from the doctors.

We had given the first demonstration to the -

- Honourable Minister (Health) on 4th March 2021
- NHM (Director) on 4th March 2021

And Second Demonstration given to the:-

- Prof. Dr, R G Baxala (HOD) RIMS on 8th September 2021
- *Prof. Dr. Sandeep Kumar Agarwal (RIMS) on 8th September 2021*
- *Dr. Anshul Kumar (CVTS Department)*

We are pleased to inform you that we have received the letter of appreciation / approval from Dr. Sandeep Agarwal & Dr. Anshul Kumar.

Fcare, Belgium has been approved by European with CE mark and by USFDA as well. This equipment is approved to import by CDSCO India. PAC certificate is attached herewith for your reference.

Novomed is exclusive, all India Authorized sole importer & Distributor for all Products of Fcare.

We are looking forward to receive your support and the order.

Yours faithfully,
Thanking You,
For NovoMed Incorporation Pvt. Ltd

Authorized Signatory

MO CSD/Dr Anshul/Dr Sandeep
Is there any RCT completing this system with connectivity?
20/11/2022

Note: CC to The Hon'ble Minister of Health & Family Welfare, Govt. of Jharkhand.

24/11/21

10/29/21, 12:03 AM Gmail - Regarding successful demonstration of Novomed EVRF.

(17)

Gmail

HEALTH MINISTER JHARKHAND <hm.jharkhand@gmail.com>

Regarding successful demonstration of Novomed EVRF.

1 message

Sandy <dreandip@gmail.com> 6 October 2021 at 10:37
To: director-rims@jharkhandmail.gov.in
Cc: hm.jharkhand@gmail.com

Respected sir
I just want to inform you that we witnessed the live demonstration of Novomed EVRF(Endovenous Radio frequency) ablation treatment for hemorrhoid, varicose vein and other venous disorders.
The demonstration was fine and the product will be useful for the mass for many venous disorders.
Thank you sir

Sincerely Yours
Surgeons unit 6
General Surgery Department
RIMS, Ranchi

11/1/21, 4:52 AM Gmail - Regarding demonstration of Novomed EVRF

Gmail

HEALTH MINISTER JHARKHAND <hm.jharkhand@gmail.com>

Regarding demonstration of Novomed EVRF

1 message

anshul kumar <docansul@gmail.com> 1 November 2021 at 03:12
To: Dr Kameshwar Prasad <director-rims@jharkhandmail.gov.in>, hm.jharkhand@gmail.com

Sir,
Humbly I would like to draw your kind attention to the EVRF(Endo Venous Radio Frequency) demonstration done by Novomed at our OPD.Our team of doctors found it promising for the treatment of Varicose veins. We have been doing treatment of Varicose vein at the Deptt and we feel that the product being demonstrated by Novomed will further help in increasing the spectrum of varicose vein treatment in that it can be used for treatment of early stages of varicose vein also.
This is for your kind knowledge and needful.
Thanking
Yours faithfully
Dr Anshul kumar
Assistant professor
CTVS
RIMS/RANCHI

(16)

NovoMed Incorporation Pvt. Ltd.
103, The Summit Business Bay, Prakashwadi, Near PVR Cinema, Village Gundavali,
Andheri Kurla Road, Andheri (East), Mumbai - 400093 Tel: 022 - 26844066 / 67 / 68
Email: info@novomed.in Website: www.novomed.in GSTIN No: 27AADCN5387P1ZN

15.12.2021

To
The Director
Rajendra Institute of Medical Science (RIMS)
Ranchi
Jharkhand

Sub: Technical Specifications & Quotation

Technical specifications:

- This system is based on the principle of radiofrequency induced thermotherapy. The MedRF4000® is an all-in-one device for the treatment of all grades of haemorrhoids, fistulas and different kinds of varicose veins – from the very small spider veins and perforating veins to Great Saphenous Vein (GSV).
- F care systems recently developed a probe for the treatment of fistulas with the same MedRF4000® device.
- All MedRF4000® treatments are based on the principle of thermocoagulation. The Principle of thermocoagulation is the heating of the vein wall by sending a high frequency signal into the tip of the catheter or needle that will make the cells vibrate so that they increase in temperature.
- It is usable in the following anatomical regions:-
    - Hemorrhoids
    - Fistulas
    - Spider Veins
    - Reticular Veins
    - Collateral Veins
    - Perforating Veins
    - Great Saphenous Veins
- The electrical resistance of a cell will be reversed by thermocoagulation. Because the needle or catheter is insulated, the effect is very local and minimal on the surrounding tissue.
- The catheters and the needles are connected to the central unit which generates the high frequency signal.
- Current is induced through a monopolar applicator.
- It is an interstitial form of therapy which can be performed under local anaesthesia.
- Tissue is heated between 80°C and 120°C using a catheter like applicator.
- It has footswitch control.
- It has catheter connectivity detection.
- It has visual and audible indication for pull-back.
- This product has become the first product of choice for haemorrhoids in Britten NHS System.
- This is CE, USFDA and DCGI approved.

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NovoMed Incorporation Pvt. Ltd.
103, The Summit Business Bay, Prakashwadi, Near PVR Cinema, Village Gundavali,
Andheri Kurla Road, Andheri (East), Mumbai - 400093 Tel: 022 - 26844066 / 67 / 68
Email: info@novomed.in Website: www.novomed.in GSTIN No: 27AADCN5387P1ZN

Sr.No.	Category	Sub- category	Specifications	Pack Size
1	Radio Frequency Generator	Monopolar RF	Generator for treatment of hemorrhoids, fistulas and varicose veins	1 Generator
2	Catheter / Probes	Hemorrhoids Probe	For the treatment of all grades of internal hemorrhoids (grades I, II, III & IV)	1 Catheter
3	Catheter / Probes	Varicose Veins Probe	For the treatment of the GSV & SSV (6- 18 mm)	1 Catheter
4	Catheter / Probes	Perforator Vein Probe	For the treatment of the Perforator Veins	1 Catheter
5	Needles	Needles	0.150 mm Diameter, for the treatment of Spider Veins	1 No. (Pack of 50 Needles)
6	Needle Holder	Needle Holder	Needle holder for the needles to treat spider veins	1 No.

Quotation:

We are pleased to offer our best rates for F care System's MedRF4000. Please find the below quotation for your reference.

SR. NO.	Ref No.	Description	Quantity	Hospital Price	Tax	Total
1	MedRF4000	EVRF Based on Thermocoagulation For the treatment of Hemorrhoids, Fistulas and all types of veins	1 No.	1759821	211179	1971000
2	K6i needle	With a 0.150 mm Diameter. Specially designed for the treatment of Spider Veins	1 No. (Pack of 50 Needles)			
3	Needle Holder	Needle holder for the K6i needles to treat spider veins	1 No.			
4	CR30i	CR30i Catheter (Diameter - 0.6 mm) with metal tip Specially designed for the treatment of perforator veins (2-5 mm)	1 No.			
5	CR45i	CR45i Catheter (Diameter – 1.9 mm) with active tip 5 mm Specially designed for the treatment of the GSV & SSV (6-18 mm)	1 No.			
6	HPR45i	HPR45i Catheter (Diameter - 1.9 mm) with a sharp metal tip of 1 cm Specially designed for the treatment of all grades of internal hemorrhoids (grades I, II, III & IV)	1 No.			

Prof. & H.O.D.
Surgery, RIMS

Dr. VINEET MAHAJAN
S,M.Ch.,FIACS
Pr Head
Cardiotho gery
Rajendra Institute of Medical Sciences, Ranchi-834009

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NOVOMED

NovoMed Incorporation Pvt. Ltd.

103, The Summit Business Bay, Prakashwadi, Near PVR Cinema, Village Gundavali,
Andheri Kurla Road, Andheri (East), Mumbai - 400093 **Tel:** 022 - 26844066 / 67 / 68
Email: info@novomed.in **Website:** www.novomed.in **GSTIN No:** 27AADCN5387P1ZN

Terms & Conditions:

Tax	: Total Price is inclusive of all taxes
Delivery Period	: 4-6 weeks after receiving the confirm order
Payment Terms	: 100% advance
Validity of the Quote	: 31st March 2022
Warranty	: 12 months from the date of delivery

We look forward to receive your valuable order.

Yours faithfully,
Thanking You,
For NovoMed Incorporation Pvt. Ltd.

NovoMed Incorporation Pvt. Ltd. Mumbai

Authorized Signatory

(13)

Date : 26th of June 2021

To Whom saver it may concern

Authorization Letter

Dear Sir

We are pleased to advise you that F Care Systems NV – Belgium has selected NovoMed to be its distributor for the highly qualified medical and medical-aesthetical equipment on the treatment of various types of varicose veins, haemorrhoids and anal fistulas based on the principle of thermocoagulation and NovoMed under the leadership or Mr. Nainesh Mehta will now cooperate to deliver you the best in patient care medical devices.

M/S NovoMed incorporation Pvt Ltd will quote supply products and goods and collect payment on their own accounts.

Thank you for your continued support and we look forward to ensuring that you have the optimum products to meet your patient's needs.

We, at F Care Systems NV, assure you the best of the services in terms of patient care and another step forward to support the medical fraternity.

We trust that arrangement will meet you and your patient's requirements and look forward to long term cordial relationship with your institute.

This authority letter is valid for 2 years from the date of issue this letter.

Please feel free to contact the undersigned for any further clarification.

Thanking you,

Yours Truly,

For F Care Systems

Dr. VINEET MAHAJAN
MS,M.Ch.,FIACS
Prof. & Head
Cardiothoracic & Vascular Surgery
Rajendra Institute of Medical Sciences, Ranchi-834009

F Care Systems NV
Uitbreidingstraat 42 - 46
Building de Regent
2600 Antwerpen-Belgium
Tel. +32 3 451 51 45
Email. info@fcaresystems.com

Michael Pierre
General Manager

Prof. & H.O.D.
Surgery, RIMS
Ranchi

fcare systems

12

PROPRIETARY CERTIFICATE

This is to certify that the following EVRF products to include the thermocoagulation probes Endovenous Radiofrequency Ablation (RFA) catheters using SEGMENTAL ABLATION TECHNOLOGY and the EVRF General Proprietary Products of M/s **F Care Systems NV, Uitbreidingstraat 42-46, 2600 Berchem,** Belgium

Product type : Thermocoagulator using radiofrequency ablation intended for treatment of varicose veins, spider veins, hemorrhoids and anal fistula including treatment of the great saphenous vein (vena saphena magna) and small saphenous vein (vena saphena parva).

Product name : EVRF , MedRF4000

Product type : Sterile Invasive radiofrequency thermocoagulation probes as accessory for thermocoagulator EVRF

Product name: CR30KAB, CR40i, CR45i, 6F, 7F, 8F, 9F and HPR45i

Are proprietary products of M/s **F Care Systems NV** Belgium

It is further certified that M/s Novomed Incorporation Pvt Ltd is Authorized importers and suppliers of the above products in India

The product design and specifications are property of and controlled by M/s **F Care Systems** Belgium

Authorized Signatory

Steven Mertens

Quality manager

Company Seal

Dr. VINEET MAHAJAN
MBBS,MS,M.Ch.,FIACS
Professor & Head
Cardiothoracic & Vascular Surgery
Rajendra Institute of Medical Sciences, Ranchi-834009

PROF. & H.O.D.
Surgery, RIMS
Ranchi

F Care Systems NV
Uitbreidingstraat 42 - 46
Building de Regent
2600 Antwerpen-Belgium
Tel. +32 3 451 51 45
Email. info@fcaresystems.com

K130283 (11)

PAGE 1 OF 3

510(k) Summary

MAR 7 2013

SPONSOR

Company Name:	F Care Systems NV
Company Address:	Kontichsesteenweg 54 2630 Aartselaar Belgium
Telephone:	011 32 3 45151245
Fax:	011 32 3 4515139
Contact Person:	Rudi Devers
Summary Prepared	September 18, 2012

Device Name

Trade Name:	EVRF
Common/Usual Name:	Electrosurgical Coagulation Device
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	ONQ
Device Class:	Class II
Regulation Number:	21 CFR 878.4400

Predicate Device

Company	***Product***	***510(k) #***
Newlands Clinical Trials LTD	Veinwave TC3000	K083352

Device Description

The EVRF has 2 major parts: 1) the generator and 2) the needle. The generator creates the impulse. The impulse can be set at between in 0.1 second increments. The combination of these two settings means that highly accurate doses of energy can be delivered. The system utilizes a current of 4MHz .The power and impulse values are accurately maintained by a microprocessor and displayed on a LCD screen. The values can be digitally adjusted. The ultra-fine needle (Product Code KCW) has a diameter of 0.075 mm allowing for accurate operation and is protected by a specific isolating sheath. The vessel is thermocoagulated without damaging the epidermis and surrounding tissue. Needles are nickel. In case of a nickel allergy, gold needles are also available. The needles are disposable and can be used for a complete session. The combination of the generator and insulated needle allows for a very precise amount of energy to be delivered to exactly the right place.

Indications for Use

The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

Summary of Technological Characteristics

The EVRF method of action is the delivery of a controlled dose of high frequency energy to the vein, which stops the flow of blood to the area of concern. Once the flow of blood is interrupted, the appearance of the spider veins is greatly reduced or eliminated.
The power generator controls through a micro-controller the delivery of stable energy to the needle and creates the impulse. The system utilizes a current of 4MHz. The impulse can be set between 0.1 seconds and 0.8 second in 0.1-second increments. The power can be set between 1 watt and 25 watt in 1-watt increment for more precision in the treatment.

The remote control has been replaced by a touch screen display allowing an easy access to the function of the EVRF.

The number of impulse per second can be set to 1 or 2 impulses per second
The casing of the unit has been redesigned for marketing and ergonomic purposes only.
None of these improvements in design and technology are raising any new issues of safety or effectiveness

The needles used with this device are not cleared as a part of this device system, as they are a Class I, 510(k) exempt device (FDA Product Code KWC).
Needles are purchased from Ballet Technologies, Ltd,
Establishment Registration # 3005114964, as sterile, single-use, disposable needles and are device listed by Ballet as accessories to Needle-Type, High Frequency Epilators Classification Code KCW.

Conclusion: The information discussed above demonstrates that the EVRF device is substantially equivalent to the predicate device and does not raise new issues of safety and effectiveness.

12.2 Predicate Product Comparison Table

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
510(k) Number		K083352
Classification and Product Code	878.4400 Product Code ONQ	878.4400 Product Code ONQ

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
Indications for Use	The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.	The Weinwave TC3000 System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.
OTC or Rx	Rx	Rx
Mode of Action	Thermocoagulation of tissue by administration of high frequency energy	Thermocoagulation of tissue by administration of high frequency energy
Mode of Delivery	Disposable Epilation Needle	Disposable Epilation Needle
Disposable Epilation Needle	Identical – Ballet Technologies LTD	Identical – Ballet Technologies LTD
Modality	Monopolar	Monopolar
Frequency (Monopolar)	4 MHz	4 MHz
Power Output – monopolar balanced at 500 ohms	25 watt	25 watt

12.3 Differences

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
Frequency (Monopolar)	4 MHz	4 MHz

Software

The level of concern was determined to be moderate. The software information provided in this 510(k) followed the requirements found in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* Issued May 11, 2005.

Safety Testing

The EVRF has passed the requirements for IEC 60601-1 and IEC 60601-1-2 EMC and 60601-2-2 electrical safety testing.

Comparison bench testing was performed –

- Comparison of output power setting and pulse setting was presented to establish substantial equivalence.

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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

Underwriters Laboratories, Incorporated
% Mr. Ned Devine
Senior Staff Engineer
333 Pfingsten Road
Northbrook, Illinois 60062

March 7, 2013

Re: K130283
Trade/Device Name: EVRF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: ONQ
Dated: February 06, 2013
Received: February 27, 2013

Dear Mr. Devine:

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 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/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,

Peter D. Rumm -S

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

Enclosure

(6)

Indications for Use Form

Indications for Use

510(k) Number (if known): K130283

Device Name: EVRF System

Indications for Use:

The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Surgical Devices Division Sign-Off 510(k) Number: K130283	Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300036905 Date: 2013.03.07 14:33:44 -05'00'