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

January 16, 2014

Microscopy, Division of Neo-Flo, Inc.
Ms. Peggy Gober
Quality Manager
3120 Moon Station Road, NW
Kennesaw, GA 30144

Re: K131799
Trade/Device Name: Quicknit
Regulation Number: None
Regulation Name: Retraction Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: November 12, 2013
Received: November 13, 2013

Dear Ms. Gober:

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,

Kwame O. Ulmer -S for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131799

Device Name: Quicknit Cord
Indications for Use:

Quicknit Cord is unimpregnated cord for the temporary retraction of the gingival margin.
The gingival retraction cord is placed in the sulcus (between the gum tissue and your tooth structure) to displace the gum tissue for a small period of time in dental procedures.

Professional use is recommended

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2014.01.09
14:23:33 -05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Sincerely yours,

for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K131799

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	<Michael E. Adjodha>
Branch Chief Sign-Off	Susan Runner
Division Sign-Off	Kwame O. Ulmer -S 2014.01.16 11:09:17 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)…" Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful…" Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known): K131794

Device Name: Quicknit Cord
Indications for Use:

Quicknit Cord is unimpregnated cord for the temporary retraction of the gingival margin.
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Professional use is recommended

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2014.01.09
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800-235-1863 PH
770-425-5715 PH
770-423-4996 FX

K131799

June 25, 2013

To Whom It May Concern:

Re: K131799

Enclosed is a replacement copy of our traditional 510(K) submission. The original was submitted June 14, 2013 without an ecopy. The ecopy is enclosed and formatted as per your instructions.

The device name is Quicknit. It is a 100% cotton retraction cord. The cord is unimpregnated. The cord is substantially equivalent to Ultrapack cord manufactured by Ultradent (K010070). Ultra offers their cord both impregnated and unimpregnated. Microcopy only offers our cord unimpregnated. Retraction Cord is unclassified and the product cord isi MVL.

The ecopy is an exact duplicate of the paper copy.

For any questions regarding this submission please contact Peggy Gober, Quality Manager, at Microcopy Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Best Regards,

Peggy Gober

Peggy Gober

Clinical Eval also on drive U20-

40

K131799

MICROCOPY
INNOVATIONS FOR DENTISTRY

Replacement Copy

6/24/13

K131799

FDA CDRH DMC
JUN 25 2013
Received

June 20, 2013

To Whom It May Concern:

Enclosed is a replacement copy of our traditional 510(K) submission. The original was submitted June 14, 2013 without an ecopy. The ecopy is enclosed and formatted as per your instructions.

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For any questions regarding this submission please contact Peggy Gober, Quality Manager, at Microcopy Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Peggy Gober

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K131799

FDA CDRH DMC
JUN 21 2013
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Peggy Gober

K13/799

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770-425-5715 PH
770-423-4996 FX

510(k) Cover Letter

June 14, 2013

To Whom It May Concern:

Enclosed is a traditional 510(K) submission. The device name is Quicknit. It is a 100% cotton retraction cord. The cord is unimpregnated. The cord is substantially equivalant to Ultrapak cord manufactured by Ultradent (K010070). The only difference between the two cords is that Ultrapak is a cotton cord that is impregnated with aluminum chloride gel. Retraction Cord is unclassified and the product code is MVL.

For any questions regarding this submission please contact Peggy Gober, Quality Manager, at Microcopy, Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Sincerely,

Peggy Gober

Peggy Gober

80

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MICROCOPY
3120 MOON STATION ROAD
KENNESAW
GA 30144
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Revi Jackson
2.1 E-MAIL ADDRESS
revi@microcopydental.com
2.2 TELEPHONE NUMBER (include Area code)
770-425
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
05-Jun-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K_____

Date: June 14, 2013
To: The Record
From:

Office:
Division:

510(k) Holder: Microcopy, Div. of Neo-Flo Inc.
Device Name: Quicknit
Contact: Peggy Gober
Phone: 770-425-5715
Fax: 770-423-4966
Email: prgober@microcopydental.com

(Please see the red italic text for instructions on how to complete the review memorandum.)

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce (device name) into interstate commerce.
(Please give a brief discussion of the 510(k), a summary of the history of the file, your recommendation and rationale of why you made your recommendation.)

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)			
Truthful and Accuracy Statement			
510(k) Summary or 510(k) Statement			
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?			
Is the device an implant (implanted longer than 30 days)?			
Does the device design use software?			
Is the device sterile?			
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			

(Describe the purpose for the 510(k): modification to a currently marketed device, new feature,

new product line, etc. Provide a summary about the device design, how it operates or performs its intended function, all important performance characteristics, etc.)

IV. Indications for Use

(Please state the Indications for Use. Give a brief description of how the new indication differs from the predicate device's indication.)

V. Predicate Device Comparison

(Provide a comparison between the subject device and the predicate device(s) with respect to intended use/indications for use, and technological characteristics.)

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

(Describe any specific labeling required for this device and discuss all claims made. Compare with the predicate device labeling.)

VII. Sterilization/Shelf Life/Reuse

(Please see "Review Template: Sterile Devices in Premarket Notification (510(k)) Submissions" to evaluate and document the sterilization information. For additional information, see the "Updated 510(k) Sterility Review Guidance K90-1".)

VIII. Biocompatibility

(Please provide a list in tabular format of the materials (including adhesives) that contact the patient. For each material, list how the biocompatibility was determined. For additional information, please see "Biocompatibility Initial Evaluation Tests for Consideration".)

IX. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

(For each checkbox, please provide a brief description indicating if the information provided is adequate. Please ensure that complete software documentation has been provided, and describe how the traceability matrix links software requirements, specifications, hazards and validation, verification and testing activities. Please see "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for additional information on reviewing software.)

X. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

(Please indicate whether the sponsor completed adequate testing per ISO 60601-1, ISO 60601-1-2 and any other relevant standards.)

XI. **Performance Testing – Bench**

(Please provide a discussion of the performance testing provided/needed.)

XII. **Performance Testing – Animal**

(Please provide a discussion of the performance testing provided/needed.)

XIII. **Performance Testing – Clinical**

(Please provide a discussion of the performance testing provided/needed.)

XIV. **Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See the Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. **Deficiencies**

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" and "A Suggested Approach to Resolving Least Burdensome Issues."

XVI. **Contact History**

(Please include all correspondence pertaining to the submission.)

XVII. **Recommendation**

Regulation Number: 21 CFR XXX.XXXX *[Only one regulation can be used.]*
Regulation Name:
Regulatory Class: Class I, II, III, or Unclassified *[Should correspond to regulation.]*
Product Code: XYZ *[Note: The first code should correspond with the regulation and class thereafter, multiple product codes can be used even if they fall under a different regulation and class.]*

_____ _____

Reviewer Date

_____ _____

Branch Chief Date

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K131799

June 20, 2013

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800-235-1863 PH
770-425-5715 PH
770-423-4996 FX

510(K) Submission
Quicknit Cord®

Indication for Use

510(K) Number: none at this time

Device Name: Quicknit Cord®

Indications for Use:

Quicknit Cord is unimpregnated cord for the temporary retraction of the gingival margin.

Over the Counter Use X
(21CFR Part 807 Subpart C)

Peggy Gober
Quality Manager
Microcopy, Div. of Neo-Flo Inc.

Perry L. Parke
President
Microcopy, Div. of Neo-Flo, Inc.

MICROCOPY
INNOVATIONS FOR DENTISTRY
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770-425-5715 PH
770-423-4996 FX

Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21CFR 807.92.

I. Applicant's Name and Address

Microcopy, Div. of Neo-Flo Inc.
3120 Moon Station Rd. NW
Kennesaw GA 30144-9017

Contact Person:	Peggy Gober
Title:	Quality Manager
Phone:	770-425-5715
Fax:	770-423-4996
Date Prepared:	5 June 2013

II. Name of the Device:

Trade Name:	Quicknit™
Common Name:	Cord, Retraction
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

Quicknit Cord is substantially equivalent to Ultrapak Neha (K010070), manufactured by Ultradent Products, Inc., which is cleared under dental device product code MVL (cord, retraction). Quicknit Cord is substantially similar to the predicate device in indications for use, physical properties, method of application and removal.

IV. Device Description:

Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted]

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770-425-5715 PH
770-423-4996 FX

Premarket Notification 510(K) Statement

I certify that, in my capacity as President of Microcopy, Div. of Neo-Flo Inc., I will make available all information included in this premarket notification on safety and effectiveness within of 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Perry L. Parke

June 14, 2013

Premarket Notification 510(k) number

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770-425-5715 PH
770-423-4996 FX

Premarket Notification Truthful and Accurate Statement

I certify that, in my capacity as President of Microcopy, Div. of Neo-Flo Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Perry L. Parke

June 14, 2013

Premarket Notification Number

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Class III Summary and Certification

I certify that, in my capacity as President of Microcopy, Div. of Neo-Flo Inc. that Quicknit™ Cord is not a Class III product.

Perry L. Parke
President
Microcopy, Div. of Neo-Flo Inc.

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Financial Certification or Disclosure Statement

In my capacity as President of Microcopy, Div. of Neo-Flo Inc. I certify that Microcopy has not conducted any clinical studies on the Quicknit Cord.

Perry L. Parke
President

June 14, 2013

MICROCOPY
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[illegible]
3120 Moon Station Road • Kennesaw, GA 30144 USA
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PO Box 2[illegible] • Kennesaw, GA 30[illegible]

800 235-1862
770-425-5711
770-423-4996

DECLARATION OF CONFORMITY

We, Microcopy Dental,

Located at: 3120 Moon Station Rd., Kennesaw, GA. 30144, USA
Declare on our own responsibility that our quality system meets the requirements of the EC Council Directive 93/42 EEC, Annex V-EC Declaration of Conformity: Production Quality Assurance, which apply to them.

The devices covered under this declaration of conformity (DOC) are:
QuicKnit retraction cord

According to Annex I and Annex VII of the above directive, the above mentioned devices are classified as class I.

Applicable standards and normative documents that were followed to confirm product's Conformity; with the Essential Requirement of the above mentioned Directive's. Annex I and Annex VII are detailed within our Technical file.

Notified Body name, address and identification number:
Name: MDC (medical device certification) GmbH; Address: Kriegerstabe 6, 70191 Stuttgart, Germany, Identification number: 0483.

European Representative:
DENTEQ Medical Technologies, Hafenstrasse 12,
76344 Eggenstein-Leopoldshafen,
Germany
Phone: +497247944842, Email: info@den-teq. Com,
Contact Person: Darrell Tuxford

Expiry date of this DOC: February 2017

Q.A. Manager
Peggy Gober

Date: 5/29/13

President
Perry L Parke

Date: 5/29/13

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Executive Summary

Following is description and intended use:

Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted]

Characteristic	Comparison Product (Ultrapak Neha)	Quicknit Cord
Intended Use		Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted]
Intended User	Dental Professional	Dental Professional
Chemical Characteristics	Aluminum Chloride Gel	None
Recommended Contact Time	1-3 minutes	Quicknit retraction cord in unimpregnated (100% cotton). Dental professional may leave in as long as required.
Physical Properties	Impregnated Cotton Cord	Unimpregnated 100% Cotton Cord

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Device Description

- Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted].

Substantial Equivalence Discussion

Characteristic	Comparison Product (Ultrapak Neha)	Quicknit Cord
Intended Use		Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted]
Intended User	Dental Professional	Dental Professional
Chemical Characteristics	Aluminum Chloride Gel	None
Recommended Contact Time	1-3 minutes	Quicknit retraction cord in unimpregnated (100% cotton). Dental professional may leave in as long as required.
Physical Properties	Impregnated Cotton Cord	Unimpregnated Cotton Cord
Quicknit cord is the same as Ultrapak cord except with no medication.		

(b)(4) Trade Secret Process- Draft Label

(b)(4) Trade Secret Process - Product Specs

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Sterilization & Shelf Life

In my capacity as President of Microcopy, Div. of Neo-Flo Inc, I certify that Quicknit Cord is not sold sterile and does not have a shelf life.

Perry L. Parke
President

June 14, 2013

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Biocompatibility

In lieu of performing biocompatibility testing we are certifying that our Quicknit™ retraction cord is comprised of identical materials to Ultrapak Neha (K010070) and are processed by identical manufacturing methods. The difference is that Quicknit is not impregnated with any medication. It is simply 100% cotton cord.

Perry L. Parke
President

June 14, 2013

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Software

In my capacity as President of Microcopy, Div. of Neo-Flo Inc. I certify that Quicknit does not contain any software.

Perry L. Parke
President

June 14, 2013

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Electromagnetic Compatibility and Electrical Safety

In my capacity as President of Microcopy, Div. of Neo-Flo Inc. I certify that Quicknit does not contain any electronic components.

Perry L. Parke
President

June 14, 2013

(b)(4) Trade Secret Process

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Performance Testing - Animal

In my capacity as President of Microcopy, Div. of Neo-Flo Inc. I certify that no performance testing was done on animals to test Quicknit.

Perry L. Parke
President

June 14, 2013

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Michael E. Adjodha

Subject: 510(k) Number K131799

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21	X	
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	None
Class:	Unclassified
Product Code:	MVL
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Susan Runner DDS, MA Mary S. Runner -S 2014.01.09 14:06:17 -05'00'
Division Sign-Off	Kwame O. Ulmer -S 2014.01.16 11:05:02 -05'00'

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K131799/S001

K131799

FDA CDRH DMC
OCT 23 2013
Received

22

October ~~11,~~ 2013

To Whom It may Concern:

Enclosed is a replacement copy of our last 510K() submission corrections. All are pdf files. All have prefix numbers as requested. There are no other files on drive. We apologize for the file on drive you received called nmdsdcid This was an error.

We have numbered these to correspond with original submission numbers. Hopefully this is acceptable.

The device name is Quicknit. It is a 100% cotton retraction cord. The cord is unimpregnated. The cord is substantially equivalent to Ultrapack cord manufactured by Ultradent (K010070). Ultra offers their cord both impregnated and unimpregnated. Microcopy only offers our cord unimpregnated. Retraction cord is unclassified and the product code is MVL.

The ecopy is an exact duplicate of the paper copy.

For any questions regarding the submission please contact Peggy Gober, Quality Manager, at Microcopy Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Best Regards,

Peggy Gober

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K131799/S001

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K131799

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OCT 15 2013
Received

October 11, 2013

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Best Regards,

Peggy Gober

4

K131799/S1

Traditional 510K Table of Contents
QuicKnit™

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October 11, 2013

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Best Regards,

Peggy Gober

Traditional 510K Table of Contents
QuicKnit™

Indications for Use

510(k) Number (if known):

Device Name: Quicknit Cord
Indications for Use:

Quicknit Cord is unimpregnated cord for the temporary retraction of the gingival margin.
The gigival retraction cord is placed in the sulcus (between the gum tissue and your tooth structure) to displace the gum tissue for a small period of time in dental procedures.

This product does not require a prescription for use. Professional use is recommended

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

There were no prior submissions for same subject device (Quicknit Cord).

Peggy Gober
Quality Manager
Microcopy

Device Description

Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process [redacted]

(b)(4) Trade Secret Process [redacted]

Differences Analysis

Following is description and intended use:
Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process - Product Specs

Characteristic	Comparison Product (Ultrapak Neha)	Quicknit Cord
Intended Use	Ultrapak is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation.	Quicknit is a dental retraction cord product made to be used specifically to retract gingiva tissue and prevent fluid from saturating the sulcus during a crown preparation. Quicknit retraction cord is made of 100% cotton that has not been impregnated with hemostatic solutions such as aluminum chloride or epinephrine hydrochloride. (b)(4) Trade Secret Process - Product Specs
Intended User	Dental Professional	Dental Professional
Chemical Characteristics	Aluminum Chloride Gel	None
Recommended Contact Time	1-3 minutes	Quicknit retraction cord is unimpregnated (100% cotton). (b)(4) Trade Secret Process - Product Specs
Physical Properties How do Differences effect the Safety & Effectiveness of Quicknit?	Impregnated Cotton Cord	Unimpregnated 100% Cotton Cord Being unimpregnated has no effect on the safety & effectiveness of the cord.

(b)(4) Trade Secret Process- Draft Label

Specifications of Quicknit cord by each size:

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K131799/S002

FDA CDRH DMC

NOV 13 2013

Received

K131799

November 12, 2013

To Whom It may Concern:

Enclosed is corrections of our last 510K() submission. All are pdf files. All have prefix numbers as requested.

001_Quicknit Insert This is the package insert you requested.

(b)(4) Trade Secret Process - Product Specs

003_Ecopy statement This is this letter.

The device name is Quicknit. It is a 100% cotton retraction cord. The cord is unimpregnated. The cord is substantially equivalent to Ultrapack cord manufactured by Ultradent (K010070). Ultra offers their cord both impregnated and unimpregnated. Microcopy only offers our cord unimpregnated. Retraction cord is unclassified and the product code is MVL.

For any questions regarding the submission please contact Peggy Gober, Quality Manager, at Microcopy Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Best Regards,

Peggy Gober

Peggy Gober

CO

(b)(4) Trade Secret Process-Draft Label

(b)(4) Trade Secret Process - Product Specs

K131799

November 12, 2013

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For any questions regarding the submission please contact Peggy Gober, Quality Manager, at Microcopy Div. of Neo-Flo Inc. Email address is prgober@microcopydental.com

Best Regards,

Peggy Gober