K040314

AUG 1 2 2004

510(k) SUMMARY

Applicant Name and Address: ENCOLL Corp.
4576 Enterprise St., Fremont, CA-94538

Contact Person: S. Gunasekaran, PhD

Date of Summary: 1-10-2004

Device Common Name: Dressing, wound, Collagen

Device Trade Name: HELICOLL

Device Classification Name: **Collagen Wound Dressing**
Unclassified

Product Code: **KGN**

Substantial Equivalence Statement:

Helicoll is a collagen wound dressing device similar to predicate collagen-based devices that are previously approved by the agency and allowed for marketing towards the management of wounds.

Such predicate devices are listed below:

SkinTemp® Kollagen Particles, K913023

Medifil® Kollagen Particles, K910944

Collatek® Powder, KO12990

HeliDermTM Collagen Wound Dressing, K990086

hyCure® Advanced Collagen Wound Care, US5506

Fibracol™ Collagen-Alginate Dressing, K925548

Fibracol Plus™ Collagen-Alginate Dressing, K982597

CollagenDressing, K03721

SIS Wound Dressing II, by Cook Biotech, K993948

The proposed device is another collagen wound dressing that is quite similar with respect to the indications for use, the major material and the physical construction to the above devices in terms of the substantial equivalency under the 510(k) regulations.

Description of the Device

Helicoll is a translucent, off-white, semi-occlusive, self-adhering and ready to use pre-sterilized Type-I Collagen Sheet for Second-degree Burn, Chronic Ulcers and other topical Wound Managements. Helicoll is flexible with moderate tackiness.

Helicoll is a reconstituted collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins (refer to the US Patents below:)

1. 6,548,077(2003) Titled: Purifying type I collagen using two papain treatments and reducing and delipidation agents.
2. 6,127,143(2000) Titled: Preparation of purified and biocompatible collagen using two proteolytic enzyme treatments and a reducing agent
3. 5,814,328(1998) Titled: Preparation of collagen using papain and a reducing agent.

Helicoll maintains a physiologically moist microenvironment at the wound surface. This device is intended for one time use only.

Indications or the Intended Uses of the Device:

Helicoll is intended for the topical wound management that includes:

- Partial and full-thickness wounds.
- Pressure ulcers.
- Venous ulcers.
- Chronic vascular ulcers.
- Diabetic ulcers.
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence

Summary Comparison of Technical Characteristics

Collagen Topical Wound Dressing and its predicates have similar technological characteristics. In particular, the Collagen Topical Wound Dressing and its predicates are similar with respect to intended use, material, form, shape, etc.

Safety and Efficacy

Collagen Topical Wound Dressing has been evaluated by the following tests to monitor its safety and biocompatibility.

1) In vitro Hemolysis (Rabbit RBCs)
2) Cytotoxicity – Agarose Overlay

3) Intracutaneous Toxicity (Rabbits)

4) Dermal Sensitization – Maximization (Guinea Pigs)

5) Muscle Implantation (Rabbits – 1 week)

6) Acute Systemic Toxicity (Mice)

7) USP Pyrogenicity (Rabbits)

8) Mutagenecity (AMES) Test

9) Muscle Implantation (Rabbits – 13 weeks)

10) Embryonic Cytotoxicity

Additional tests conducted are:

Acute Oral Toxicity (Mice)

Systemic Antigenecity (Guinea Pigs)

Skin irritation (Rabbits)

LAL Chromogenic Assay

Heavy Metal analysis

(Please find the detailed protocol and the results in the Appendix of the original submission)

Helicoll has passed all applicable testing for the biological evaluation of medical devices.

Conclusion

The results of the ***in vitro*** product characterization studies and biocompatibility studies indicate that Helicoll, the Collagen Topical Wound Dressing, is safe and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Subramanian Gunasekaran, Ph.D.
President
Encoll Corporation
5686 Geranium Court
Newark, California 94560

Re: K040314
Trade/Device Name: Helicoll
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 28, 2004
Received: June 29, 2004

Dear Dr. Gunasekaran:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 040314

Device Name: HELICOLL

Indications For Use:

The Healicoll Topical Collagen Wound Dressing is intended for the topical wound management that includes:

- Partial and full-thickness wounds.
- Pressure ulcers.
- Venous ulcers.
- Chronic vascular ulcers.
- Diabetic ulcers.
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears),
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

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

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number K040314

[redacted]

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Encoll Corporation
4576 Enterprise St
Fremont, CA 94538

LICENSE NUMBER: 50637
EXPIRATION DATE: 9/17/2026

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Encoll Corp.

LTF No.: LTF130416

Date: April 16, 2013

Letter-to-File Form Cover Page

Modified/ New Product	Name:	Helicoll
	Part No.:	FG HC 0.5 dia, HC 0.8x10, HC 1.0 dia, HC 2x2, HC 2x4, HC 4x4, HC 4x6, HC 4x8, HC 4x10, HC 6x6, HC 6x8, HC 6x12, HC 6x18, HC 6x26, HC 8x8, HC 8x10, HC 8x12, HC 8x16, HC 10x18, HC 12x12, HC 16x16, HC 24x24, & HC custom size
	Model.:	Sterile Collagen membrane
Product Being Modified	Name:	Helicoll
	FDA 510(k) No.:	K040314
	Model:	Sterile Collagen membrane

Previous LTFs Affecting Product Being Modified:	LTF No.:	n/a	LTF No.:	n/a
	LTF No.:	n/a	LTF No.:	n/a
	LTF No.:	n/a	LTF No.:	n/a

Device Classification:	☐ Class I ☐ Class II ☐ Class III ☒ Unclassified
Device Product Classification Code (including Branch):	KGN
Device Listing Number (or Listing Number for Devices with the Same Product Classification Code):	KGN
CDRH Laser Report Accession Number (if applicable):	n/a

Cleared Indications for Use:

The Helicoll product is indicated for partial and full thickness wounds, pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, trauma wounds (abrasions, lacerations, second degree burns, skin tears), surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)

Conclusion of Regulatory Evaluation:	☒ Letter to File ☐ New FDA 510(k) required, documents retained for evidence of review only

Signature Approvals for Letter to File and for any required Supporting Engineering Data or Documentation

Reviewed & Approved By:	Name	Title	Signature	Date
Originator/ Approver	Subramanian Gunasekaran, Ph.D.	President/CEO	S. Gunasekaran	4/16/2013

Regulatory FDA Non-Filing Decision & Justification Document

I. Existing Product Description:

Helicoll is a translucent, off-white, semi-occlusive, self-adhering and ready to use pre-sterilized Type-I Collagen Sheet for Second-degree Burn, Chronic Ulcers and other topical Wound Managements. Helicoll is flexible with moderate tackiness.

Helicoll is a reconstituted collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins. Refer to the U.S. Patents below:

- 1.6,548,077(2003) Titled: Purifying type I collagen using two papain treatments and reducing and delipidation agents.
- 2.6,127,143(2000) Titled: Preparation of purified and biocompatible collagen using two proteolytic enzyme treatments and a reducing agent
- 3. 5,814,328(1998) Titled: Preparation of collagen using papain and a reducing agent.

Helicoll maintains a physiologically moist microenvironment at the wound surface. This device is intended for one time use only.

II. Description of Proposed Change(s):

In addition to the above, Helicoll™ Topical Collagen Wound Dressing product description can also be referred to as a **Bioengineered Acellular Constructs** or **as a Biological Skin Substitute** or as an **Acellular Dermal Replacement Matrix**.

III. Reason for Change(s):

The purpose of the change to Helicoll product description is to use all such additional characterizations of the product. The new product descriptions are consistent with several other, currently existing, similar acellular dermal replacement and bio-engineered skin substitute products.

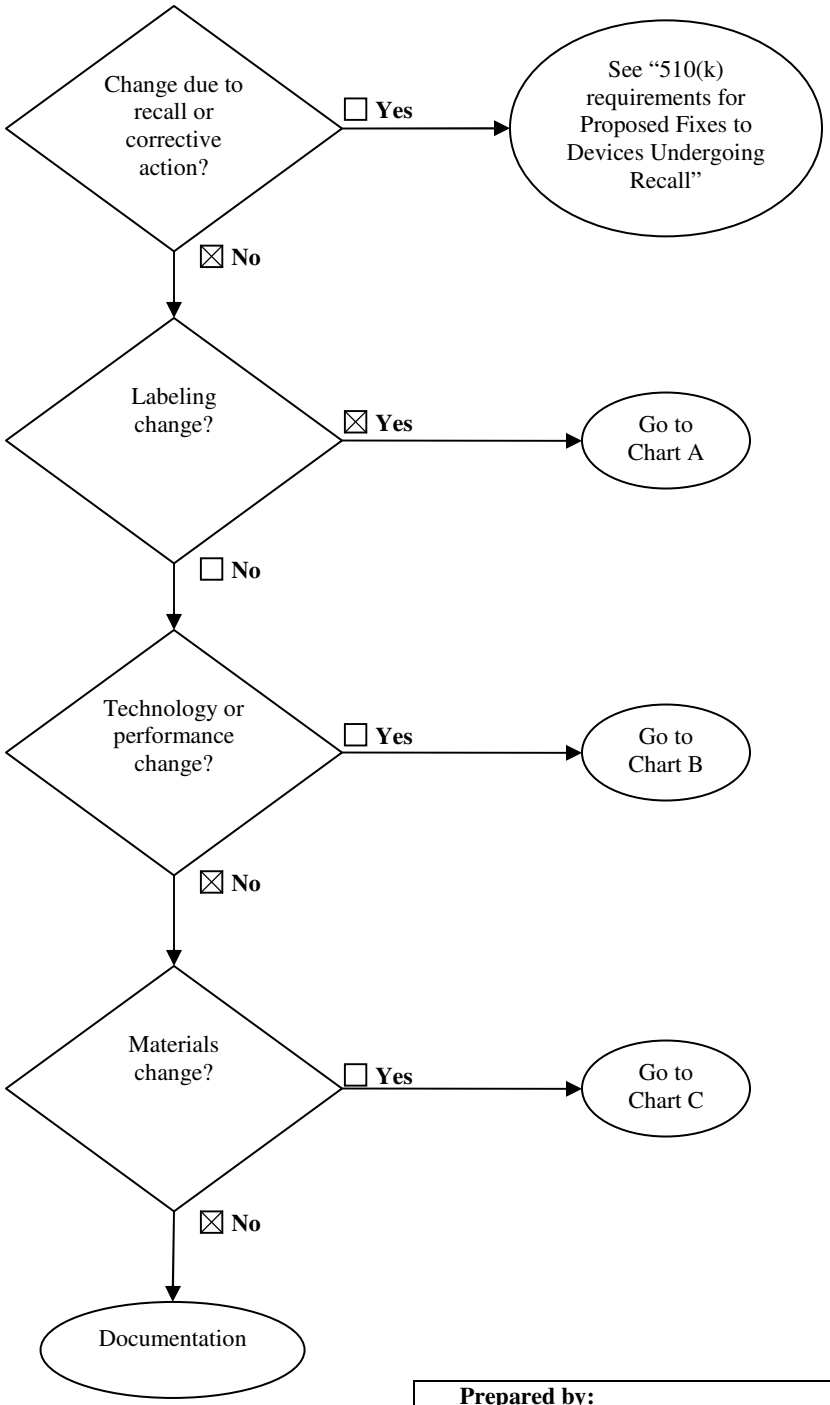
On 01-01-2012 the AMA issued new CPT codes 15271 and 15272. These new codes recognize the application of a skin substitute composed of acellular bioengineered constructs to treat an open wound. Helicoll is a bioengineered high purity Type-1 collagen product and is manufactured by Encoll using patented processes to form a >97 % pure acellular construct that is highly bioactive, cell conductive, and supportive towards enhancing tissue generation.

Attachment 1 provides Table I, which shows the product comparison between Helicoll™ and other acellular dermal replacement products with 510(k) and Table II, which shows the technological characteristics between Helicoll™ and the other compared acellular dermal replacement products.

Considering the guidelines provided by FDA regarding “when to file a 510(k) after change to a legally marketed device” (see the two charts below), appropriate Letter to File has been implemented.

The differences between Helicoll™ and similar devices do not alter the indications for use, do not raise new questions of safety or effectiveness; and thus, do not affect the safety or effectiveness of Helicoll™ for their intended use. The purpose of the change to Helicoll product description is to include the other descriptive features of the product as an acellular dermal replacement construct and a bioengineered skin substitute or matrix.

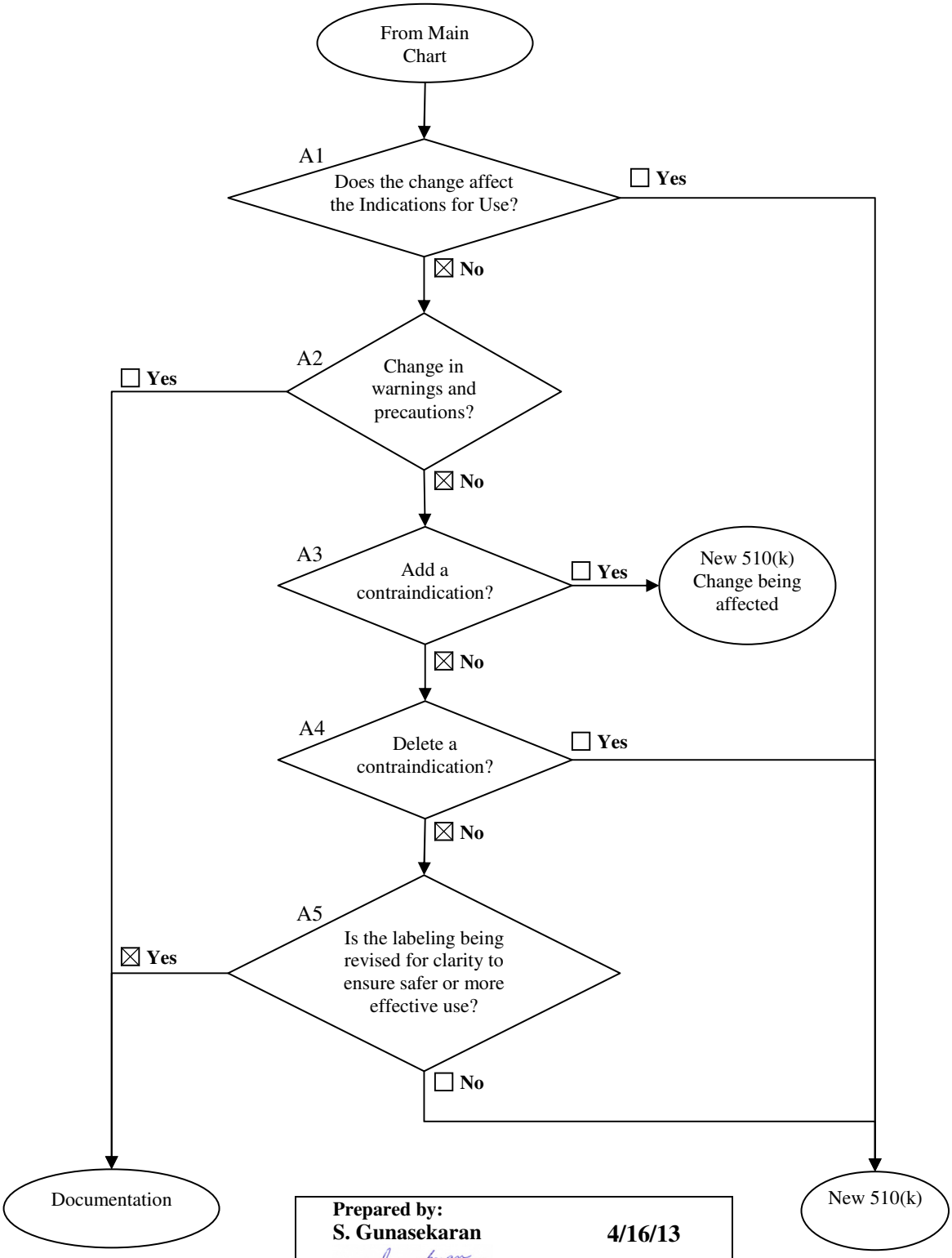
Main Flowchart
When to File a 510(K) After Change to a Legally Marketed Device



Prepared by:
S. Gunasekaran **4/16/13**

Signature Date

Flowchart A – Is it a Labeling Change?



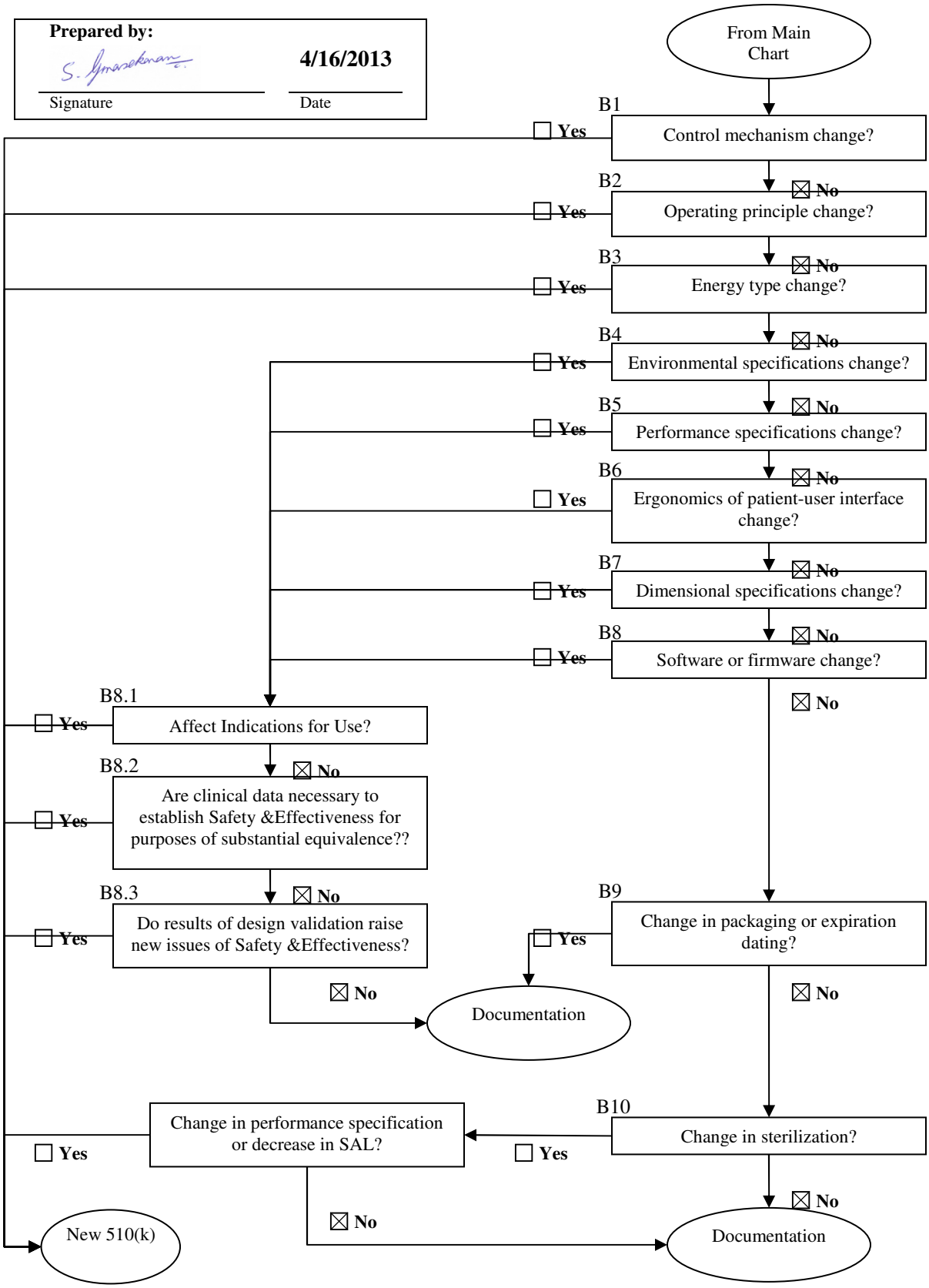
Prepared by:
S. Gunasekaran **4/16/13**

S. Gunasekaran

Signature Date

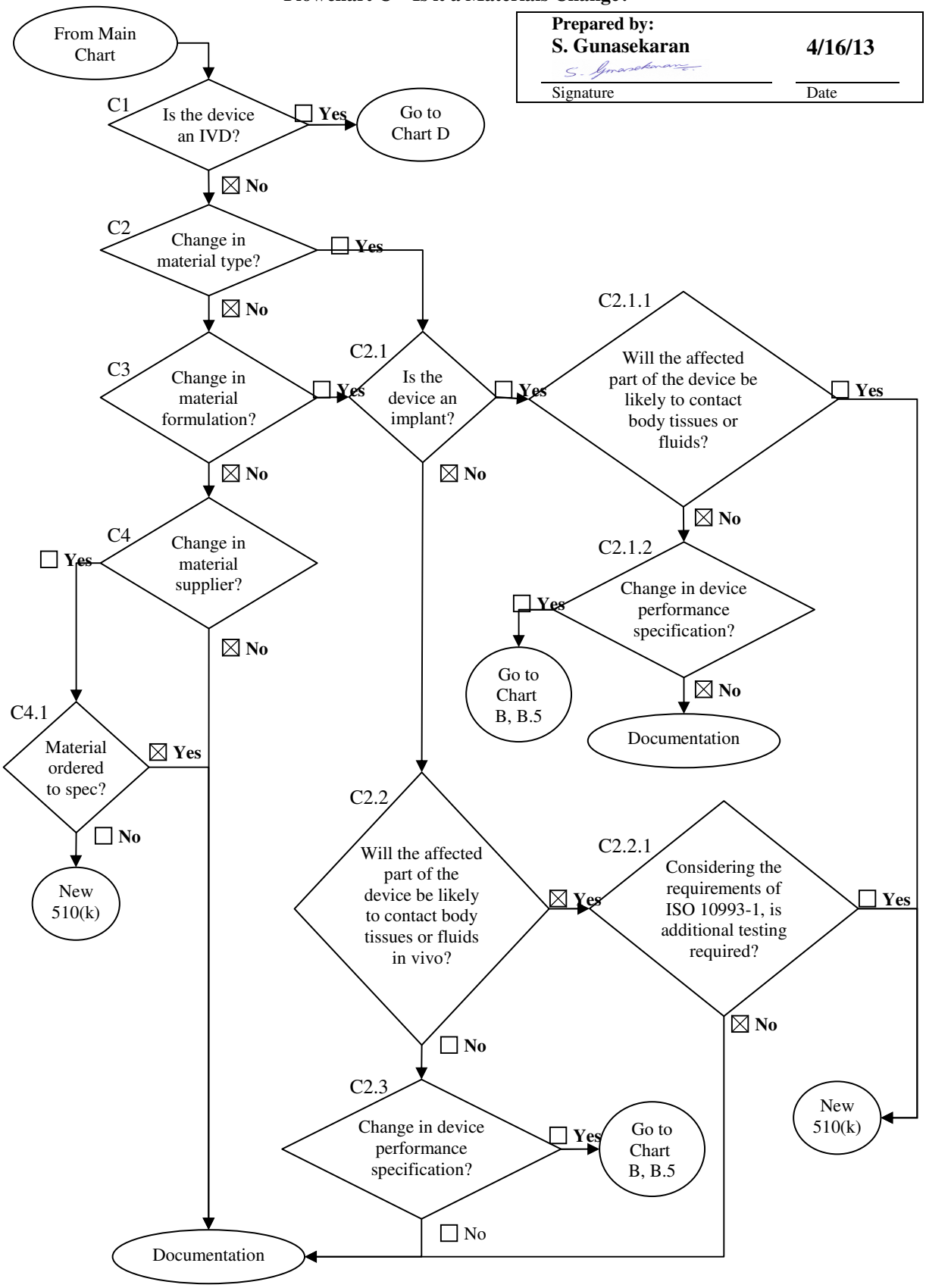
Flowchart B – Is it a Technology or Performance Change?

Prepared by: S. Gnanasekaran **4/16/2013**
Signature Date



Flowchart C – Is it a Materials Change?

Prepared by: **S. Gunasekaran** **4/16/13**
Signature Date



IV. Regulatory Filing Decision

According to the above questions and the flowchart paths, is a new 510(k) submission required?

☐ Yes -If "Yes", skip the remainder of this form and sign the cover sheet
☒ No - If "No" complete the remainder of this form

V. Justification for Changes/ Modifications including copies of documentation when necessary to support conclusion (select appropriate items being justified)

Labeling		
A1	Does the change affect the indications for use?	No Yes –
A2	Is it a change in warnings or precautions?	No Yes –
A3	Does the change add a contraindication?	No Yes –
A4	Does the change delete a contraindication?	No Yes –
A5	Is the labeling being revised for clarity to insure safer or more effective use?	No Yes – Refer to Section III above
Technology/ Performance		
B1	Is it a control mechanism change?	No Yes –
B2	Is it an operating principle change?	No Yes –
B3	Is it a change in energy type?	No Yes –
B4	Is it a change in environmental specifications?	No Yes –
B5	Is it a change in performance specifications?	No Yes –
B6	Is it a change in ergonomics of the patient/user interface?	No Yes –
B7	Is it a change in dimensional specifications?	No Yes –
B8	Is it a change in software or firmware?	No Yes –
B8.1	Does the change affect the indications for use?	No Yes –
B8.2	Are clinical data necessary to evaluate safety and effectiveness for purposes of determining substantial equivalence?	No Yes –
B8.3	Do results of design validation raise new issues of safety and effectiveness?	No Yes –
B9	Is there a change in packaging or expiration dating?	No Yes –
B10	Has there been a change in sterilization?	No Yes –
B10.1	Has there been a change in performance specification of the device or in the sterility assurance level attained as a result of the change in sterilization?	No Yes –
Materials		
C1	Is the device an in vitro diagnostic product (IVD)?	No Yes –
C2	Is this a change in the type of material from which the device is manufactured?	No Yes –
C2.1	Is the device an implant?	No Yes –
C2.1.1	If an implant - Will the material of the affected part of the implant be likely to contact body tissues or fluids?	No Yes –
C2.1.2	Is there a change in device performance specifications?	No Yes –
C2.2	Will the material of the affected part of the (non-implant) device be likely to	

V. Justification for Changes/ Modifications including copies of documentation when necessary to support conclusion (select appropriate items being justified)	
contact body tissues or fluids in vivo?	
C2.2.1 Considering the material is likely to contact in vivo body fluids and the requirements of ISO 10993-1, is additional testing required?	No Yes –
C2.3 Is there a change in device performance specifications?	No Yes –
C3 Is there a change in the formulation of the material, but not a change in material type?	No Yes –
C4 Is there a change in the vendor of the raw material from which the device is manufactured?	No Yes –
C4.1 Is the new material being supplied to a specification?	No Yes –
	No Yes –

VI. Supporting Documentation – Attach or Reference File Location as Appropriate				
Appendix No. (if provided)	**Document**	**Required?**	**Document Attached?**	**Location of Document if Not Attached**
Appendix 1	Additional Product Description from Section I (if necessary)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 2	Additional Description of Proposed Change from Section II (if necessary)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 3	Additional Description of Reason for Change(s) from Section III (if necessary)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 4	Regulatory Contact/Memo Reference		☐ Yes ☒ No	**NA**
Appendix 5	Labeling Change(s)	☒ Yes ☐ No	☒ Yes ☐No	**Attachment 1 and 2**
Appendix 6	Technology or Performance Change(s)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 7	Material(s) Change(s)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 8	Product Specification (redline & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 9	DFU/ Operator Manuals - Labeling (redlines & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 10	Product/ System Labels - Labeling (redlines & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 11	Marketing Literature - Labeling (redlines & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 12	Schematics (redline & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 13	Final Test Procedure	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 14	Performance Data (Final, verification, qualification & validation, stability, etc.)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 15	Environmental Qualification/ Validation	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 16	Hazard Analysis (redline & new)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 17	Software Information:	☐ Yes ☒ No	☐ Yes ☒No	**NA**
	• SRS – Software Requirements Spec	☐ Yes ☒ No	☐ Yes ☒No	**NA**
	• SDD – Software Design Document	☐ Yes ☒ No	☐ Yes ☒No	**NA**
	• Completed Validation Plan V&V ▸ With Traceability Matrix	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 18	Biocompatibility Test Report (s) and/or Adoption Memo(s)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 19	Cleaning Validation Test Report (s) and/or Adoption Memo(s)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 20	Sterilization Validation Test Report(s) and/or Adoption Memo(s)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 21	Packaging Information, Qualification, Validation (Expiration Dating if applicable)	☐ Yes ☒ No	☐ Yes ☒No	**NA**
Appendix 22	Statement of Veracity of Data Provided by Functional Groups	☐ Yes ☒ No	☐ Yes ☒No	**NA**

VII. Additional Appendices Documentation

Appendix 1 - Additional Product Description from Section I (if necessary)

NA

Appendix 1 - Additional Description of Proposed Change(s) from Section II (if necessary)

NA

Appendix 2 - Additional Description of Reason for Change(s) from Section III (if necessary)

NA

VII. Additional Appendices Documentation - Continued

Appendix 22 - Statement of Veracity of Data Provided by Functional Groups

We certify that, to the best of our knowledge, all technical data and information provided in support of this Letter-to-File is truthful and accurate and that no material facts have been omitted.

1. R&D/Engineering Information (check applicable): ☒ NA
   ☐ Product specification(s) ☐ Schematics ☐ Performance data ☐ Hazard analysis
   ☐ Software documentation ☐ Cleaning validation ☐ Other (specify):

Printed Name	Title	Signature	Date

2. Operations/Manufacturing Information (check applicable): ☒ NA
   ☐ Final test procedure ☐ Sterilization validation ☐ Packaging qualification ☐ Shelf-life/Expiration
   ☐ ☐ ☐ Other (specify):

Printed Name	Title	Signature	Date

3. Quality Assurance Information (check applicable): ☒ NA
   ☐ Final test data ☐ Biocompatibility ☐ ☐
   ☐ ☐ ☐ Other (specify):

Printed Name	Title	Signature	Date

4. Technical Publications / Sales & Marketing (check applicable): ☐ NA
   ☐ User's manual ☐ Marketing brochure(s) ☒ Product Labeling ☐ Other (specify):

Printed Name	Title	Signature	Date
Subramanian Gunasekaran, Ph.D.	President / CEO	S. Gunasekaran	4/16/13

Letter to File LTF130416
Attachment 2

Table I – Product Comparison

Product	HELICOLL (EnColl Corp)	Endoform Dermal Template™ (Mesynthes Ltd).	Integra Bilayer Wound Dressing (Integra LifeSciences)	MatriStem® Wound Matrix (ACell, Inc.)	SIS Wound Dressing II (Cook Biotech)	OASIS® Ultra Tri-Layer Matrix (Cook Biotech)	Primatrix (TEI Biosciences)	Primatrix (TEI Biosciences)	Unite Biomatrix® (Synovis Orthopedic)
510(k) Date	K040314 8/2004	K092096 1/2010	K021792 8/2002	K112409 8/2011	K993948 1/2000	K061711 7/2006	K061407 6/2006	K083440 12/2008	K112399 7/2011
Device Description (Effective material)	Purified Type I Collagen Acellular Matrix Xenograft	Ovine Collagen Xenograft	Bovine collagen & Gag Xenograft with a silicone layer	Porcine urinary Bladder Xenograft	Porcine intestine Xenograft	Porcine intestine Xenograft	Bovine dermal collagen Xenograft	Bovine dermal collagen Xenograft	Equine pericardial matrix crosslinked Xenograft
Product Code	KGN	KGN	KGN	KGN	KGN	KGN	KGN	KGN	KGN
Regulatory Classification	unclassified	unclassified	unclassified	unclassified	unclassified	unclassified	unclassified	unclassified	unclassified
Intended / Indication for Use	Partial and full thickness wounds, pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, trauma wounds (abrasions, lacerations, second degree burns, skin tears), surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)	Partial and full thickness wounds, pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and draining wounds	Partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and draining wounds	Partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and draining wounds	Partial and full thickness wounds, pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, surgical wounds trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and draining wounds	Partial and full thickness wounds, including pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, tunneled undermined wounds, surgical wounds, trauma wounds and draining wounds	Partial and full thickness wounds, pressure, diabetic, and venous ulcers second degree burns, surgical wounds-donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence, trauma wounds-abrasions, lacerations, and skin tears, tunneled undermined wounds, draining wound	Partial and full thickness wounds, pressure, diabetic, and venous ulcers second degree burns, surgical wounds-donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence, trauma wounds-abrasions, lacerations, and skin tears, tunneled undermined wounds, draining wound	Moderately to severely exudating wounds, including: partial and full thickness wounds, draining wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wound (e.g., abrasions, lacerations, partial thickness [second degree} burns, skin tear and surgical wounds (e.g., donor sites/grafts, post laser surgery, post Moh's surgery, podiatric wounds, dehisced surgical incisions)
HCPCS Code	A6021-23 Eligible for Q41xx Code	C9367	Q4104	Q4119	A6021-23	Q4102	A6021-23	Q4110	Q4129

Letter to File LTF130416
Attachment 2

Table II. Technological Characteristics

ATTRIBUTE	COMMONALITY	DIFFERENCE	IMPACT
Design	Biological construct, Bio-engineered skin substitute used as a graft or a non-graft, Dermal Repair Scaffold or Matrix, Acellular dermal replacement product, made of collagen from other animal source like bovine and considered as a xenograft	Helicoll is claimed as +97% Pure Type I bovine collagen, uncrosslinked, using patented manufacturing process. Other products may have lesser Purity of collagen, presence of other collagen types and other biological molecules in the final constructs, may be cross-linked.	No impact
Functional Performance and Design	All products are indicated for Partial and full thickness wounds, pressure ulcers, venous ulcer, diabetic ulcer, chronic vascular ulcers, trauma wounds (abrasions, lacerations, second degree burns, skin tears), surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence). Accordingly is is designed as a membrane that can be sutured or stapled at the edges for retention purposes and also can accept secondary dressing(s).	No significant difference noted.	No impact
Materials	Animal-derived extra cellular matrix. As the major component of ECM is collagen, all products may have collagen as a common material.	The collagen source may differ between bovine, porcine etc.. Other products may have lesser Purity of collagen, presence of other collagen types and other biological molecules in the final constructs, may be cross-linked.	No Impact
Biocompatibility	Biocompatible for all the indications allowed by FDA (see 510K clearance document)	No significant difference	No Impact. All product materials have been proven to be biocompatible.
How Supplied	Sterilized package	No significant difference	No Impact.

Letter to File LTF130416
Attachment 2

510(k) Document Links:

Integra
http://www.accessdata.fda.gov/cdrh_docs/pdf2/k022127.pdf

Integra Bilayer Wound Matrix
http://www.accessdata.fda.gov/cdrh_docs/pdf8/K021792.pdf

Sis Wound Dressing II
http://www.accessdata.fda.gov/cdrh_docs/pdf/K993948.pdf

Oasis wound matrix
http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061711.pdf

Endoform Dermal Matrix
http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092096.pdf

Unite Biomatrix
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