DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2015

Biologics Therapies Incorporated
c/o Mr. Stephen Inglese
Quality Solutions and Support, LLC
5817 North West 44th Avenue
Ocala, Florida 34482

Re: K141910
Trade/Device Name: Intraosseous Cannula System Bio-MAC™ and Bio-CORE™
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: April 24, 2015
Received: April 27, 2015

Dear Mr. Inglese:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141910

Device Name
Intraosseous Cannula System - Bio-MAC™ and Bio-CORE™

Indications for Use *(Describe)*
The Bio-MAC™ Bone Marrow Aspiration Cannula System is for use in the intraosseous aspiration of viscous bone marrow material in the human body.

The Bio-CORE™ Bone Marrow Biopsy Cannula System is for use in the intraosseous harvest and biopsy of "solid core" bone marrow material in the human body.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (8/14) Page 1 of 1

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Intraosseous Cannula Systems is provided below.

Device Common Name: Biopsy Instrument

Device Proprietary Name: Intraosseous Cannula System Bio-MAC™ and Bio-CORE™

Submitter: Biologics Therapies, Inc.
5817 NW 44th Avenue
Ocala, FL 34482
(352)-304-5149

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Date Prepared: January 10th 2015

Classification Regulation: 876.1075 – *Gastroenterolgy- Urology Biopsy Instrument*
Panel: Gastroenterology / Urology
Product Code: KNW - Subsequent Code: FCG

Predicate Device: *K072045 – ONCONTROL Bone Marrow Biopsy System*

Indication for Use:
The Bio-MAC™ Bone Marrow Aspiration Cannula System is for use in the intraosseous aspiration of viscous bone marrow material in the human body.

The Bio-CORE™ Bone Marrow Biopsy Cannula System is for use in the intraosseous harvest and biopsy of "solid core" bone marrow material in the human body.

Device Description:
The Bio-MAC™ Bone Marrow Aspiration Cannula System is an 11 gauge cannula needle system in various lengths (currently 25,45,60,80 and 105mm) that allows the use of a surgical drill "power driver" for hard bone insertion during a viscous bone marrow aspiration/collection procedure.

The Bio-CORE™ Bone Marrow Biopsy Cannula is an 11guage cannula needle system in various lengths (currently of 60, 80, and 105mm) that allows

the use of a surgical drill "power driver" for hard bone insertion during a bone marrow solid core biopsy procedure.

Indication Statement Comparison:

Predicate Device: K072045 - *OnControl Bone Marrow Biopsy System*
Indications - The OnControl Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy.

Submitted Devices:
Bio-MAC - The Bio-MAC™ Bone Marrow Aspiration Cannula System is for use in the intraosseous aspiration of viscous bone marrow material in the human body.

Bio-MAC - The Bio-CORE™ Bone Marrow Biopsy Cannula System is for use in the intraosseous harvest and biopsy of "solid core" bone marrow material in the human body.

Summary Indication Comparison:
No Deviations - The submitted devices indications are in line with the predicate device. The submitted devices accomplish either bone marrow aspiration or bone marrow biopsy as similarly stated in the predicate indication.

Summary of technological characteristics / Substantial Equivalence–
The predicate and the Intraosseous Cannula Systems Bio-MAC™ and Bio-CORE™ were compared in the following areas and found to have similar technological characteristics and to be equivalent to the Vidacare OnControl Bone Marrow Biopsy System :

- Indications for use
- Needle Design (Material and Gauge)
- Technique
- Sterility
- Single Use
- Anatomical Location

Summaries of technological characteristics demonstrating substantial equivalence (SE) (BTI Bio-MAC and BTI Bio-CORE with SE Vidacare OnControl are also provided below:

BTI - Bio-MAC device as compared to the Vidacare – OnControl Bone Marrow Biopsy System -

Device Characteristic	**Biologics Therapies (BTI)**	**Vidacare**
Device Name	Bio-MAC	OnControl Bone Marrow Biopsy System
510(k) Number	K141910	K072045
Material	304 Stainless Steel / Polyetherimide (Ultem)	304 Stainless Steel
Diameter – gauge	11	11
Length - mm	25, 45, 60, 80, 105mm	25, 60, 90 and 102mm
Cannula Fenestration Slots	Yes	No
Packaged Sterilized	Yes	Yes
Single Use Device	Yes	Yes
Method of Device Insertion	Drill / Driver; via a provided driver adapter – customer owned drill – example Stryker Surgical Instruments and Accessories – K943323	Drill / Driver; via a provided re-useable battery powered drill
Method of aspiration	Attached syringe to Luer Lock on cannula hub	Attached syringe to Luer Lock on cannula hub
Skeletal Location of Use	Proximal Humerus, Proximal Tibia, Posterior Iliac Crest, Anterior Iliac Crest and Vertebral Body	Proximal Humerus, Proximal Tibia, Distal Tibia and Iliac Crest

BTI - Bio-CORE device as compared to the Vidacare – OnControl Bone Marrow Biopsy System -

Device Characteristic	Biologics Therapies	Vidacare
Device Name	Bio-CORE	Oncontrol Bone Marrow Biopsy System
510(k) Number	K141910	K072045
Material	304 Stainless Steel / Polyetherimide (Ultem)	304 Stainless Steel
Diameter – mm	11	11
Length – mm	60, 80 and 105mm	102 and 152mm
Packaged Sterilized	Yes	Yes
Single Use Device	Yes	Yes
Method of Device Insertion	Drill / Driver; via a provided driver adapter – customer owned drill – example Stryker Surgical Instruments and Accessories – K943323	Drill / Driver; via a provided re-useable battery powered drill
Skeletal Location of Use	Iliac Crest	Iliac Crest

Performance Testing :
To establish the substantial equivalence of the Intraosseous Cannula Systems Bio-MAC™ and Bio-CORE™ devices the following performance tests were performed:

- 027_A6_Bio-MAC Design Validation PROT / RPT 300
- 028_A6_Bio-CORE Design Validation PROT /RPT 301
- 029_A6_Predicate Device Testing - Bio-MAC Design Validation PROT / RPT 301
- 030_A6_Bio-MAC Physical Testing – Torque to Turn and Pullout Tests

The results indicated the submitted devices perform as safe and effective as the predicate device.

Performance Testing Summary:
Utilizing a predicate device of the largest size and the BTI Bio-MAC and Bio-CORE smallest and largest size bench testing was accomplished. The two tests demonstrated that utilizing the BTI Bio-MAC and Bio-CORE in an operating condition demonstrated the devices functioned as safe and

effective as the predicate device thus the Bio-MAC and Bio-CORE are recognized to be substantially equivalent.