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

July 19, 2017

XPress BCD, LLC
Peter Kremers, M.D.
6024 White Flint Drive
Frederick, MD 21702

Re: K163388
Trade/Device Name: XPress BCD Breast Compression Device
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray System
Regulatory Class: Class II
Product Code: POY
Dated: June 9, 2017
Received: June 12, 2017

Dear Dr. Kremers:

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" (21 CFR 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,

Jennifer R. Stevenson -S3

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

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)*
K163388

Device Name
XPress BCD®

Indications for Use *(Describe)*
The Xpress BCD is a reusable device indicated for use with stereotactic biopsy platforms to apply temporary focal mechanical compression to a stereotactic breast biopsy site to achieve hemostasis.

Rx Only. Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

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K163388 510(K) SUMMARY

July 17, 2017

1.0 SPONSOR

Peter Kremers, MD (Contact person)

6024 White Flint Drive Frederick, MD 21702

T: 301.401.5853

E: peterkremers@comcast.net

2.0 NAME OF DEVICE

Trade name: XPress BCD® Breast Compression Device

Common name: Post Breast Biopsy Hemostatic Breast Compression Device

3.0 CLASSIFICATION OF DEVICE

Classification: Class II Product Code: POY

Regulation Number: 892.1710

Classification Panel: Radiology

4.0 PREDICATE DEVICE

Device Trade Name: Biopsy Digit S and Biopsy Digit SL

510(k) Control Number: K113607 Product Code: IZH

Manufacturer: Giotto USA, LLC, Wichita, KS

5.0 INDICATIONS FOR USE

The Xpress BCD is a reusable device indicated for use with stereotactic biopsy platforms to apply temporary focal mechanical compression to a stereotactic breast biopsy site to achieve hemostasis. Rx Only. Federal (USA) law restricts this device to sale by or on the order of a physician.

6.0 DEVICE DESCRIPTION

The XPress BCD device is an accessory used in conjunction stereotactic breast biopsy devices.

The XPress BCD is comprised of Delrin® DuPont (acetal homopolymer resin, Delrin 150NC010), or similar material. There are three (3) independent XPress BCD device configurations that are provided as a set: configuration 1 (large flat), configuration 2 (modified pyramidal), and configuration 3 (modified spherical). These different configurations are used based on the biopsy site being treated. The Xpress design includes a mechanical slot for attaching to compression paddles of mammographic x-ray systems

The XPress BCD is used in conjunction with the XPress BCD Cover (K863853; classification JAA; manufactured by Preferred Medical Products, Ducktown, TN). It is used to enclose the XPress BCD for use as intended. The XPress BCD Cover, is a sterile, single-use covering. The XPress BCD Cover is a 4 X 5 inches covering of a 0.002 mm thick polyethylene blend material, and its closure system is a round or oblong synthetic rubber band made of a polyisoprene polymer, measuring 2 X 1/8 X 1/16 inches. The XPress BCD Cover is packaged with the XPress BCD or may be purchased separately.

7.0 BIOCOMPATIBILITY

The Xpress BCD device does not come in direct or indirect contact with the patient as intended for use. Biocompatibility testing has not been performed on the XPress BCD.

8.0 STERILIZATION AND CLEANING

The XPress BCD is a non-sterile, reusable device. The Xpress BCD device does not come in direct or indirect contact with patients during breast biopsy procedures. The Xpress BCD compression device is to be covered by a sterile, single-use XPress BCD Cover prior to use as intended.

The XPress BCD device, without protective covering, must be cleaned, disinfected, and inspected prior to use on a patient, including between biopsies on the same patient, using an EPA-registered disinfectant that achieves intermediate level of disinfection with a tuberculocidal claim.

9.0 CLINICAL TESTING

A prospective historical control single arm clinical study (NCT02327598) was conducted at one investigational site to evaluate the performance of the XPress BCD breast compression device to obtain hemostasis after stereotactic-guided breast biopsy following 120 biopsies in 118 female subjects with mammographic findings that warranted stereotactic biopsy. Five investigators and six assistants participated in this study; the 118 enrolled and treated subjects met the following inclusion criteria:

- Adult women: eighteen years of age and older.
- Sites of calcification (size not restricted) and/or breast lesions (masses) ≤ 1.5 cm in diameter deemed suspicious by radiologist/ breast surgeon.
- Provided written informed consent.

None of the 118 enrolled and treated subjects met the study's criteria for exclusion:

- Pregnancy.
- Lactation.
- Cognitive impairment.
- On active blood thinners including, but not limited to, warfarin, clopidogrel and heparin. Low dose aspirin or non-steroidal medication are not subject to this requirement.
- A known bleeding disorder or uncorrected coagulopathy with a platelet count of ≤ 80,000 and/or an international normalized ratio of ≥ 1.5.

- Note : Coagulation parameters were not routinely performed unless suspicion of coagulopathy including known deficiencies such as Factor Vlll and Xl, Diffuse Intravascular Coagulation, Uremia, Liver Failure, Myeloproliferative Disorder, Alpha 2 Antiplasmin deficiency, Monoclonal Gammopathy, and Lupus Anticoagulant).

Follow-up after discharge included phone contact after 24 hours and 7 days. Patients were asked to return if they developed significant bruising greater than 3 cm in diameter, a new lump at the biopsy site, increasing pain, or signs of infection including redness, increased warmth, or increased temperature. Returning patients out to one week were evaluated clinically as well as with ultrasound of the biopsy site.

Additionally, all 65 of the 120 original biopsy sites deemed evaluable for evidence of fat necrosis were reviewed at one year. Evaluable sites required the absence of interval surgical biopsy/lumpectomy and mammograms available for review at one year following biopsy and mechanical compression.

The primary clinical performance measure / adverse effect were hematoma formation. Hematoma was defined as a new three dimensional mass (> 0.52 cm^3) detected on standard post-biopsy full- field mammography. Incidence and size of delayed hematomas were also noted. Unanticipated adverse events were defined as any serious adverse effect on health, safety, or any life-threatening problem or death caused by or associated with the device. No unanticipated adverse events were noted during the course of the study and follow-up evaluation.

Table 9-1 summarizes demographics and performance measures for 120 biopsy procedures performed on 118 enrolled and treated clinical study patients. Immediate post-compression hematoma was detected by primary investigators in 9/120 biopsies (7.5%). Additional delayed hematomas detected out to one week after biopsy were found following 4/120 (3.2%) of the biopsies. No mammographic evidence of fat necrosis was noted at one-year post-biopsy in a subgroup of 65 subjects who had not been subject to open biopsy or lumpectomy and were evaluated with mammography at one year post-biopsy. All biopsy sites meeting the criteria for evaluation were assessed for mammographic for evidence of fat necrosis by both the primary study and independent mammographers.

Table 9-1. Demographics and Performance Measures across 118 Patients and 120 Biopsy Sites

Measure	Age (yrs)	Breast Density	Breast Compression (mm)	Calcs/ Other*	Cores	Compression Time (min)	Hematoma	Hematoma Size (cm^3)	Delayed Hematoma	Fat Necrosis
Total				80/ 40			9/120 (7.5%)		4/120 (3.3%)	0/65
Average	57	2	65		9.8	11		4.4		
Range	34-79	1-4	30-103		5-24	10-20		1.0-12.1	Occurred on days 2, 5, 7, 7	

*80 sites were clusters of calcification. 40 sites were other targets, including masses, densities, and sites of architectural distortion.

Table 9-2 provides the results from two independent mammographers' examinations; one found hematomas on immediate post-biopsy imaging following 7/120 (5.8%) of biopsy procedures and the other in 9/120 (7.5%). Neither noted any mammographic evidence of fat necrosis in the 65 subjects who did not proceed to open biopsy or lumpectomy and for whom mammography at one year post-biopsy was available for review.

Table 9-2. Independent Imaging Review across 118 Patients and 120 Biopsy Sites

Reviewer	Hematoma	Average Hematoma Size (cm^3)	Fat Necrosis
A	7/120 (5.80%)	5.6	0/65
B	9/120 (7.5%)	5.7	0/65

Of the 120 original biopsy sites, 65 were evaluable for evidence of fat necrosis as surgical biopsy/lumpectomy had not been performed and mammograms were available for review at one year following biopsy and mechanical compression.

Table 9-3 presents assessments reported by study staff and the 118 subjects. Most assessments are reported per biopsy site (N=120), however, post-study satisfaction was reported per patient (N=118).

Table 9-3. Staff and Subject Reported Outcomes across 118 Patients and 120 Biopsy Sites

	Staff-Reported Evaluation	Subject-Reported Pain			Subject-Reported Satisfaction		
		Procedure	Compression	Post	0-hour	24-hour	1-7 day
# Biopsy Sites	120	120	120	120	120	115/118 patients	113/118 patients
Average	5	2	0.9	0.3	1.3	1.3	1.2
Criteria Rang	-5= extreme degradation 5= extreme enhancement	0 = no pain 10 = sever pain			1 = great experience 5 = poor experience		

Note: Staff evaluation compared their impressions on the use of mechanical compression on workflow relative to the use of standard manual compression using a 10 point scale (-5 extreme degradation to +5 extreme enhancement of workflow). The effect on workflow closely mirrored staff estimates of net time saved or lost (in minutes) relative to standard manual compression (assuming that they would have been responsible for performing manual breast compression).

10.0 SUBSTANTIAL EQUIVALENCE FEATURES

During breast biopsy procedures, the XPress BCD is used to apply direct mechanical compression to the biopsy site, as a replacement for standard manual compression. The XPress BCD is inserted into the stereo guide compression paddle, and pressure is applied mechanically by the paddle and attached XPress BCD device. Before insertion into the compression paddle, the XPress BCD is placed inside, and enclosed by, a sterile XPress BCD Cover, so that the device does not come in direct or indirect contact with the patient. Further, sterile 4 X 4 gauze pads are placed between the covered XPress BCD device and the patient, which is an additional barrier to direct or indirect contact with the patient.

The XPress BCD Breast Compression Device, is substantially equivalent to the legally marketed, commercially available Biopsy Digit S and Biopsy Digit SL (K113607), manufactured by Giotto USA, LLC, Wichita, KS 67226. The XPress device does not introduce any technological characteristic differences that raise questions of safety or effectiveness; to establish this, a list of comparative features and their similarities and differences is provided in the table below:

Table 10 -1. Comparison of Similarities and Differences between Biopsy Digit S and Biopsy Digit SL (K113607) and XPress BCD

COMPARISON	PREDICATE DEVICE: BIOPSY DIGIT S AND BIOPSY DIGIT SL	SUBJECT DEVICE: XPRESS BCD	SUBSTANTIALLY EQUIVALENT
Intended Use	The Biopsy Digit S and SL are intended to be used for mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy and guide wire placement.	The XPress BCD is intended to be used for mammographic procedures requiring stereotactic guidance. The device is indicated for focal mechanical compression of biopsy sites to achieve and maintain hemostasis.	Yes. Intended for use in mammographic procedures requiring stereotactic guidance. SE demonstrated by well-controlled clinical trial.
Intended Population	The target population consists of female patients undergoing stereotactic guided mammographic biopsy procedures.	The target population consists of female patients undergoing stereotactic guided mammographic biopsy procedures.	Yes.
Prescription Use	Yes	Yes	Yes
Device Class	Class II	Class II	Yes
Device	System, X-Ray, Mammographic	Post Breast Biopsy Hemostatic Breast Compression Device	Yes. Regulation Description is Mammographic x-ray system. SE demonstrated by well-controlled clinical trial.
Regulation Number	21 CFR 892.1710 (a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. (b) *Classification.* Class II.	21 CFR 892.1710 (a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. (b) *Classification.* Class II.	Yes
Product Code	IZH	POY	Yes. Product Codes included in Regulation Number 892.1710. SE demonstrated by well-controlled clinical trial.
Used for mammographic procedures requiring stereotactic guidance	Yes	Yes	Yes
Regulation Description	Mammographic x-ray system.	Mammographic x-ray system.	Yes
Provided Sterile or Non-Sterile	Non-sterile	Non-sterile	Yes
Multiple use	Yes	Yes	Yes

COMPARISON	PREDICATE DEVICE: BIOPSY DIGIT S AND BIOPSY DIGIT SL	SUBJECT DEVICE: XPRESS BCD	SUBSTANTIALLY EQUIVALENT
User interface software	Yes	No	Yes. No differences in safety or effectiveness are introduced
Electro-mechanical mechanisms	Yes	Yes*	Yes.
Computer interface to store images	Yes	No	Yes. No differences in safety or effectiveness are introduced
Computer interface to determine coordinates for needle positioning	Yes	No	Yes. No differences in safety or effectiveness are introduced

*Though the subject device does not contain any electro-mechanical mechanisms, when attached to a stereotactic breast biopsy device it may be moved either manually or electro-mechanically via that device.

11.0 SUBSTANTIAL EQUIVALENCE

The XPress BCD, and the claimed predicate device, the Biopsy Digit S and Biopsy Digit SL device, are accessories used during stereotactic-guided breast biopsy procedures including breast biopsies. The XPress BCD device and the predicate device have the same general intended use – they are accessories for mammographic procedures requiring stereotactic guidance including breast biopsies. The XPress device does not introduce any technological characteristic differences that raise questions of safety or effectiveness. The XPress BCD device has been demonstrated to be as safe and effective as the predicate device for intended use in a prospective, single site single arm historical control clinical study (NCT02327598). There are no additional significant questions of safety or effectiveness.