DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 15, 2014

Intact Medical Incorporated
% Dr. John J. Smith
Hogan Lovells US LLP
555 Thirteenth Street, North West
Washington, District of Columbia 20004

Re: K142477
Trade/Device Name: *Intact*® BLES with *Intact*® Excision XL wand and handle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: November 21, 2014
Received: November 21, 2014

Dear Dr. Smith:

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,

David Krause -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

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 on last page

510(k) Number *(if known)* K142477

Device Name: ***Intact***® BLES with ***Intact***® Excision XL wand and handle

Indications for Use *(Describe)*

- The Intact® BLES with Intact® Excision XL wand and handle is indicated to provide tissue samples for diagnostic sampling of breast abnormalities
- The Intact® BLES with Intact® Excision XL wand and handle is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality
- The Intact® BLES with Intact® Excision XL wand and handle is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality
- *The Intact® BLES with Intact® Excision XL wand and handle is intended to preserve lesion architecture in samples with a diameter of 12–30mm*

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpable or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the ***Intact***® BLES with Intact® Excision XL wand and handle may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histologic evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary

Intact® BLES with ***Intact***® Excision XL wand and handle

Applicant	Intact Medical Corporation 550 Cochituate Road - Suite 25 Framingham, MA 01701 Phone: 508-655-7820 Fax: 508-655-7822
Establishment Registration Number	1226766
Contact Person	John J. Smith, M.D., J.D. Hogan Lovells US LLP 555 Thirteenth St. NW Washington, DC 20004 Phone: 202-637-3638 Fax: 202-637-5910
Summary Date	December 15, 2014
Proprietary Name	***Intact***® BLES with ***Intact***® Excision XL wand and handle
Classification	Class II
Classification Name	Biopsy Instrument and Electrosurgical Cutting & Coagulation Device & Accessories
Regulation Number	21 C.F.R. § 876.1075
Classification	Product Code KNW
Predicate Devices	10mm, 12mm, 15mm and 20mm Intact ® BLES (K060413) manufactured by Intact Medical Corporation Intact ® Advance and Intact Excision XL (K081057 "Primary Predicate") manufactured by Intact Medical Corporation

Device Description

The intent of the device is to be a biopsy tool to capture a sample of breast tissue in one intact sample to preserve the tissue architecture for histologic examination. The device is a high frequency, vacuum-assisted electrosurgical devices used to remove tissue by electro-surgical cutting and simultaneous capture of an incised tissue volume. The devices include the following components:

1. **Probe/Wand**
   (1a) ***Intact*** BLES Probe/wand
   (1b) ***Intact Advance*** BLES Probe/wand
   (1c) ***Intact Excise XL*** Probe/wand

2. **Handle**
   (2) The ***Intact*** BLES Handle
   (2a) ***Intact Excise XL*** Handle
3. ***Intact* Medical ™ Model 3000 Controller**
4. **Controller Power Cord Footpedal**
5. **Table Mount**
   (6a) Table Mount, BLES attaches the ***Intact*** BLES Handle to a stereotactic table (Fischer and Lorad mounts).
   (6b) Table Mount, ***Excise XL*** attaches the ***Intact Excise XL*** Handle to a stereotactic table (Fischer and Lorad mounts).
6. **Vacuum Source**
7. **Cart**

Probe/Wand:
The probes/wands are sterile and intended for single use. They utilize a sharp blade to access the target lesion.

The Cut/Capture Electrode is located at the distal end of the wand. It consists of five (5) small diameter wire electrodes that cut tissue with a mono-polar electro-surgical cutting current and purse down to close the distal end of the cutting/capture element to make a circumscribing incision and capture of the target tissue.

Handle:

The handles consist of a hand piece at the distal end of a cable that mates with the Probe/Wand, a connector at the proximal end of a cable that mates with the Controller, a grip provided for ultrasound hand held procedures. The grip is replaced with a cradle for stereotactically guided procedures.

Controller:

Intact Medical Model 3000 Controller consists of a radiofrequency generator, which operates at a single, preset frequency to apply a high-frequency voltage during the biopsy specimen capture phase.

Power Cord:

The Intact Controller Power Cord is a standard detachable power cord that connects the Controller to the line voltage output receptacle.

Foot Pedal:

The foot pedal assembly is a floor-mounted, three-pedal device, which attaches to the rear of the Intact Model 3000 Controller. The three pedals provide probe and handle controls to allow the user an alternate interface (to the handle buttons).

Cradle:
Multiple versions of the cradle are available to fit commercially available stereo-tactic tables.

Vacuum Source:
An off the shelf unit that allows for suction and removal of fluids during the procedure

Intended Use/Indications for Use

- The Intact® BLES with Intact® Excision XL wand and handle is indicated to provide tissue samples for diagnostic sampling of breast abnormalities

- The Intact® BLES with Intact® Excision XL wand and handle is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality

- The Intact® BLES with Intact® Excision XL wand and handle is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality

- *The Intact® BLES with Intact® Excision XL wand and handle is intended to preserve lesion architecture in samples with a diameter of 12–30mm*

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Technical and Operational Characteristics

The proposed 510k is limited to a change in label claims. No changes have been made to the device. The Intact® BLES with Intact® Excision XL wand and handle is identical in design, operational and technological characteristics as the predicate devices (K060413; K081057) and supports that no new safety concerns are being raised by change in intended use/indications for use statement and thus raises no new issues of safety or effectiveness.).

Summary of Testing

The Intact® BLES with Intact® Excision XL wand and handle was previously subjected to a comprehensive test program that included electrical safety and electromagnetic compatibility testing, animal testing, clinical testing, biocompatibility and sterilization testing. Since there is no change to the technology of the Intact® BLES with Intact® Excision XL wand and handle and the only proposed change is limited to the Indications for Use, no additional bench or animal testing was conducted to support demonstration of substantial equivalence in performance from the Intact® BLES with Intact® Excision XL wand and handle to its predicate device.

However, additional clinical data was generated to support the proposed additional indications for use claim. Complete Excision Rates were evaluated as a surrogate measure to assess the ability to remove sufficient, undisrupted tissue to preserve tissue architecture and to permit a definitive diagnosis.

Provided in the table below is a tabular summary of representative medical literature documenting the use of the Intact® BLES with Intact® Excision XL wand and handle as a tool in the field of breast biopsy.

Tabular summary of medical literature with Intact® BLES with Intact® Excision XL wand and handle

Citation	Author	Patient Quantity	Complete Excision Rate (%)
1	Whitworth, P	25	88
2	Whitworth, P, Simpson, Poller, Schonholz, Turner, Phillips, Johnson, McEachin	10	100
3	Naglaa Abdel Razek	76	76
4	Schonholz, S	37	49
5	Steven D. Allen , Ashish Nerurkar , Guidabaldo U. Querci Della Rovere	76	83
TOTAL	BLES	224	76%

Citation number:

1. Whitworth, P. Percutaneous Stereotactic Lumpectomy and Partial Breast Irradiation for Small Breast Cancers: Reducing Overtreatment Presented at: Miami Breast Meeting 2014 - Publication pending
2. Whitworth, Simpson, Poller, Schonholz, Turner, Phillips, Johnson, McEachin: Definitive Diagnosis for High-Risk Breast Lesions Without Open Surgical Excision: The Intact Percutaneous Excision Trial (IPET), Annals of Surgical Oncology (2011) 18:3047-3052
3. Naglaa Abdel Razek. Percutaneous breast lesion excision system (BLES): a new tool for complete closed excision of high risk lesions. European Congress of Radiology 2013.
4. Schonholz, S. Complete Excision and Reexcision Rates Following Percutaneous biopsy using the Intact Breast Lesion Excision System and the Mammotome. ASBS 2013 in publication for review with Journal of Surgical Oncology.
5. Steven D. Allen & Ashish Nerurkar &Guidabaldo U. Querci Della Rovere The breast lesion excision system (BLES): a novel technique in the diagnostic and therapeutic management of small indeterminate breast lesions? European Radiology 2011.

Rationale For Substantial Equivalence

The Intended Use/Indications for Use statement and technological characteristics of the Intact® BLES with Intact® Excision XL wand and handle and the predicate devices were compared. The Intended Use/Indications for Use statement of the devices have the same general claims and do not raise new questions of safety and performance. Both the predicate device and proposed 510k device capture an intact sample of tissue for histological assessment. This proposed change to the Indications for Use is well supported by a review of the peer reviewed clinical literature and society presentations and are similar to that of the predicate devices with the same general intended use.

Conclusion

Based on the similar label, identical technology and operation characteristics as well as the clinical performance testing, the Intact® BLES with Intact® Excision XL wand and handle device is substantially equivalent to the predicate devices.