



Food and Drug Administration
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February 15, 2016

Intact Medical Corporation
% Dr. John Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth St. NW
Washington, District of Columbia 22204

Re: K152596

Trade/Device Name: Intact® Gen2 System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: January 19, 2016
Received: January 19, 2016

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" (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 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

Indications for Use

510(k) Number (if known)
K152596

Device Name: **Intact**[®] Gen2 System

Indications for Use (Describe)

- The **Intact**[®] Gen2 System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.
- The **Intact**[®] Gen2 System is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality.
- The **Intact**[®] Gen2 System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.
- The **Intact**[®] Gen2 System is intended to preserve lesion architecture in samples with a diameter of 12–30 mm.

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**[®] Gen2 System 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)

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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510(k) Summary***Intact*[®] Gen2 System**

Applicant	Intact Medical, Inc.
Establishment Registration Number	1226766
Contact Person	John Vacha
	Intact Medical Corporation 550 Cochituate Road - Suite 25 East Wing, Floor 4 Framingham, MA 01701 Phone: 508-655-7820 Fax: 508-655-7822
Summary Date	February 12, 2016
Proprietary Name	<i>Intact</i>[®] Gen2 System
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 Device	<i>Intact</i>[®] BLES with <i>Intact</i>[®] Excision XL wand and handle (K142477)

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 device used to remove tissue by electrosurgical cutting and simultaneous capture of an incised tissue volume. The device includes the following components:

1. **Probe/Wand**

***Intact*[®] Gen2 Probe/wand (Sizes: 12mm, 15mm, 20mm and 30mm)**

2. **Handle**3. **Gen2 Controller with Power Cord and Foot Pedal**4. **Table Mount**

Available to fit stereotactic tables (Fischer and Lorad mounts).

5. **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 electrosurgical 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.

The wand contains a resistor of unique value for each wand size (12mm, 15mm, 20mm, or 30mm) that is used by the Controller to identify the specific wand size installed in the handle.

Handle:

The handles consist of a hand piece at the distal end of a cable that mates with the Probe/Wand, and a connector at the proximal end of a cable that mates with the Controller. The handle is either mated to a stereotactic table using a mount or handheld for ultrasound-guided procedures.

Controller:

The *Intact*[®] Gen2 Controller consists of a radiofrequency generator, which operates at a single, preset frequency. The *Intact*[®] Gen2 Controller is designed to apply a high-frequency voltage during the biopsy specimen capture phase (involving Capture Electrodes). The power applied for each wand size is optimized to (1) be sufficiently high to form the electrical arc essential to effect the highly localized vaporization of cellular fluid which, thereby, enables electrosurgical cutting and (2) be sufficiently low to minimize the depth of necrosis induced in the biopsy specimen and the surrounding tissue. The controller incorporates a microprocessor and software.

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, two-pedal device, which attaches to the rear of the *Intact*[®] Gen2 Controller. The two pedals provide the Arm and Capture functions, analogous to those buttons on the handle. Either the footswitch or the handle controls can be used interchangeably.

Cradle:

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

Cart:

This is an off-the-shelf moveable cart that houses the components of the system.

Required for the procedure but not included in the system are: An off-the-shelf vacuum unit and a patient return electrode.

Intended Use/Indications for Use

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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**[®] Gen2 System 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.

Technical and Operational Characteristics

The **Intact**[®] Gen2 System works on the same principle of operation as the predicate device. Both require setting up a high-frequency voltage between an electrosurgical electrode (*i.e.*, active electrode) and the tissue to be incised. This voltage creates an arc between the electrode and the tissue. This arc, by virtue of the high temperature, induced at the point of impingement with tissue, vaporizes the tissue in its vicinity.

This 510(k) notice implements technological modifications to the wands (addition of a resistor) and controller (addition of a microprocessor and software) to individualize the amount of power required to capture a sample based on probe size. Thus, less power is required to capture a tissue sample

for each sized probe. The proposed device is capable of performing to its intended use similar to the predicate device.

Summary of Testing

Verification Testing Summary Table			
Test Type	Proposed <i>Intact</i> [®] Gen2 System	Predicate <i>Intact</i> [®] BLES System Intact BLES (K142477)	Comments
Safety and Essential Performance Tests	Pass	Pass	Equivalent Both systems meet requirements of IEC 60601-1, 3 rd Edition and IEC 60601-2-2
EMC Tests	Pass	Pass	Equivalent Both systems meet requirements of IEC 60601-1-2
Software Verification Tests	Pass	Not applicable	Proposed software meets requirements of IEC 62304. Predicate contains no software, utilized hardware for all functions.
Usability Tests	Pass	Pass	Equivalent Both systems meet the requirements of EN 60601-1-6.
Bench Performance Verification Test	Pass	Pass	Equivalent Demonstrated that the proposed system does not deliver more total energy to the biopsy tissue sample than the predicate.
Thermal Artifact Verification Testing	Pass	Pass	Equivalent Demonstrated that the thermal artifacts in biopsy tissue samples are equivalent

Rationale for Substantial Equivalence

The proposed modifications reduce the power introduced to the patient to capture a similar intact sample (size, shape, weight, architectural integrity, thermal artifact) as that of the predicate device. The proposed device is capable of performing to its intended use similar to the predicate device.

The Intended Use/Indications for Use statement and technological characteristics of the *Intact*[®] Gen2 System device and the predicate devices were compared. The Intended Use/Indications for Use statements of the devices are identical. The proposed changes to the technology are supported by extensive bench and animal testing described above and are similar to that of the predicate device with the same intended use.

Conclusion

Based on similar technology and operation characteristics as well as the bench and animal performance testing, the *Intact*[®] Gen2 System device is substantially equivalent to the predicate device.