June 19, 2018

TransMed7, LLC
James Vetter
Chairman
117 Solana Road
Portola Valley, California 94028

Re: K173316

Trade/Device Name: SpeedBird Model SB38 Soft Tissue Biopsy Device; SpeedBird Model SBU Soft Tissue Biopsy Device; SpeedBird Model SBU99 Soft Tissue Biopsy Device

Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 23, 2018
Received: May 25, 2018

Dear James Vetter:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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
Indications for Use

510(k) Number (if known)
K173316

Device Name
SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices

Indications for Use (Describe)
The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are intended for diagnostic sampling of soft tissue during soft tissue biopsy procedures. They are to be used for diagnostic purposes only and are not intended for therapeutic uses.

The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are indicated to provide soft tissue samples for diagnostic sampling of soft tissue abnormalities, including breast, liver, kidney, prostate, spleen, lymph nodes, and various other soft tissue abnormalities. They are designed to provide soft tissue for histologic examination, with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from imaging appearance (ultrasound, radiographic, e.g., mammographic) of a soft tissue abnormality. Therefore, the extent of removal of the 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
The following information is provided as required by 21 CFR § 807.92 for the SpeedBird Family of Soft Tissue Biopsy Devices 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, a summary is provided of the safety and effectiveness information upon which the substantial equivalence determination is based.

### Device Descriptions

**SpeedBird Model SB38 Soft Tissue Biopsy Device Description**

The SpeedBird Model SB38 Soft Tissue Biopsy Device is a sterile, single-use, percutaneous electro-mechanical vacuum-assisted biopsy device used to provide soft tissue samples for histological examination with partial or complete removal of the imaged abnormality.

The handle of the device contains an on/off safety switch, 3-position actuation slide switches that are accessible from either side, a built-in red diode class II or IIIa laser pointer light, a removable specimen collection tube, a drive mechanism for advancing and rotating the coring and severing cannula, a built-in vacuum pump and tubing to augment transporting the specimen to the specimen collection tube as well as transporting any fluid aspirate to a detachable collection receptacle, a DC motor, power indicator light, and a choice of two or three internal 3V batteries.

The working end of the device includes an 88 mm or 109 mm long, 10- to 14-gauge stainless steel one-piece coring cannula including twin opposed cutter blades that both core and sever tissue samples for vacuum transport to a detachable collection chamber.
SpeedBird Model SBU Soft Tissue Biopsy Device Description

The SpeedBird Model SBU Soft Tissue Biopsy Device is a sterile, single-use percutaneous electro-mechanical vacuum-assisted biopsy device used to provide soft tissue samples for histological examination with partial or complete removal of the imaged abnormality.

The handle of the device contains an on/off safety switch; a 3-position actuation trigger that is accessible from either side and that is used to activate the motor and to cycle the twin cutter blades between coring and severing modes; and a choice of a built-in vacuum pump and tubing, or tubing only for use with external vacuum. In either choice, vacuum is utilized to augment transporting the specimen to the specimen collection tube as well as transporting any fluid aspirate to a detachable fluid collection receptacle. Also included is a DC motor, power indicator light, current rectifier, resistors, accessory attachment rail and a receptacle for input of direct or alternating electrical current.

The working end of the device includes an 88 mm or 109 mm long, 10- to 14-gauge stainless steel one-piece coring cannula including twin opposed cutter blades that both core and sever tissue samples for vacuum transport to a detachable collection chamber.

SpeedBird Model SBU99 Soft Tissue Biopsy Device Description

The SpeedBird Model SBU99 Soft Tissue Biopsy Device is a two-component biopsy device comprising a sterile, single-use percutaneous biopsy needle cassette for use within a reusable biopsy needle handle (driver).

1. The Biopsy Needle Cassette is supplied sterile and is for single-patient use only. This Biopsy Needle Cassette contains all patient contact pathways and is fully disposable. Cleaning, re-processing and/or re-sterilization of the Biopsy Needle Cassette is prohibited. The Biopsy Needle Cassette drops into the Biopsy Needle Handle (driver) and consists of the following pre-assembled, sterile components:
   a. A biopsy needle consisting of a stainless steel, one-piece coring cannula with twin opposed cutter blades that both core and sever tissue samples for vacuum transport to a detachable collection chamber;
   b. A detachable, radiolucent, surgical-grade plastic or stainless steel, coaxial outer tube that surrounds the stainless steel coring cannula and may be used to maintain access to the biopsy site for post-procedure marker placement or for intra-operative imaging; and
   c. All fluid transport tubing.

2. The Biopsy Needle Handle (driver) is supplied non-sterile and is reusable. The handle contains an on/off safety switch; a 3-position actuation trigger that is accessible from either side and that is used to activate the motor and to cycle the twin cutter blades between coring and severing modes; and a choice of a built-in vacuum pump and tubing, or tubing only for use with external vacuum. In either choice, vacuum is utilized to augment transporting the specimen to the specimen collection tube as well as transporting any fluid aspirate to a detachable fluid collection receptacle. Also included is a DC motor, power indicator light, current rectifier, resistors, accessory attachment rail and a receptacle for input of direct or alternating electrical current.
## Indications For Use

The Indications For Use statements for the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices and for the identified predicate devices are listed here, followed by a discussion of the similarities and differences between the Indications For Use.

<table>
<thead>
<tr>
<th>Device</th>
<th>Indications For Use Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices</td>
<td>The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are intended for diagnostic sampling of soft tissue during soft tissue biopsy procedures. They are to be used for diagnostic purposes only and are not intended for therapeutic uses. The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are indicated to provide soft tissue samples for diagnostic sampling of soft tissue abnormalities, including breast, liver, kidney, prostate, spleen, lymph nodes, and various other soft tissue abnormalities. They are designed to provide soft tissue for histologic examination, with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from imaging appearance (ultrasound, radiographic, e.g., mammographic) of a soft tissue abnormality. Therefore, the extent of removal of the 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.</td>
</tr>
<tr>
<td>Magic™ Breast Biopsy Device K053151</td>
<td>The Rubicor Magic™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses. The Rubicor Magic™ Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the 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.</td>
</tr>
<tr>
<td>Device</td>
<td>Indications For Use Statement</td>
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</tbody>
</table>
| **Sanarus Cassi™ II Rotational Core Biopsy System**<br>K051581 | The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors. It is not intended for use in bone.  
The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.  
The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the 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. |
| **BIP VacuFlash® Biopsy System**<br>K024089 | The BIP VacuFlash® Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.  
The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the 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. |
| **Mammotome elite® Biopsy System**<br>K153709 | The Mammotome elite® Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be readily determined from the palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sample 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 Mammotome elite® Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological 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. |
Indications for Use Comparison Discussion

The indications for use for the SpeedBird Soft Tissue Biopsy Devices are essentially the same as the identified predicate device Sanarus Cassi™ II Rotational Core Biopsy System.

The indications for use for the remaining identified predicate devices are a subset (breast tissue target organ indication only) of the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices and the Sanarus Cassi™ II Rotational Core Biopsy System.

The wording present in the Sanarus Cassi™ II Rotational Core Biopsy System, the Magic™ Breast Biopsy Device, and the BIP VacuFlash® Biopsy System Indications For Use Statements which states that:

“The extent of histologic abnormality cannot be reliably determined from its mammographic appearance.”

….has been modified in the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices’ Indications For Use Statement to state the following:

“The extent of histologic abnormality cannot be reliably determined from imaging appearance (ultrasound, radiographic, e.g., mammographic) of a soft tissue abnormality.”

Inclusion of this added wording more accurately represents the range of diagnostic imaging and/or functional diagnostic imaging procedures that are currently used for soft tissue imaging and image-guided biopsy procedures, including breast abnormalities. This modification does not affect the safety or effectiveness of the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices when used as indicated.

Technology Comparisons to Predicate Devices

Like all of the identified predicate devices listed in this 510(k) submission, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are handheld, vacuum assisted soft tissue biopsy systems designed for compatibility with imaging guidance.

As with all of the identified predicate devices, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices utilize a rotating, forward advancing coring cannula to core and sever tissue core samples for histologic analysis, which has been shown to provide more definitive information than cytological analysis alone.

Like the predicate Magic™ Breast Biopsy Device and Mammothome elite® Biopsy System devices, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are capable of single insertion-multiple sampling for procedure efficiency and accuracy as well as to minimize tissue trauma.

Similar to the Mammothome elite® Biopsy System and BIP® VacuFlash Biopsy System predicate devices, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices combine rotational coring and severing with vacuum to enhance tissue extraction from the biopsy site.

As with the Magic™ Breast Biopsy Device and the Sanarus Cassi™ II Rotational Core Biopsy System predicate device, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices utilize open forward-end coring to reduce sampling error to improve imaging-histologic concordance.

As with the Sanarus Cassi™ II Rotational Core Biopsy System predicate device, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are indicated for the same soft tissue biopsy indications and procedures.

Like the Magic™ Breast Biopsy Device predicate device, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices have a detachable tissue receptacle to receive cored tissue samples.

510(k) Summary of Premarket Notification for the SpeedBird Soft Tissue Biopsy Devices (K173316), Revised 14 June 2018
Additionally, the SpeedBird devices’ tissue receptacle is a specimen collection tube that automatically keeps the received samples in sequential order to further improve imaging-histological correlation and enhance concordance between the two.

Like the Mammotome elite® Biopsy System predicate device, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices incorporate fluid and tissue management using vacuum to augment transport of core samples as well as any fluid aspirate from the biopsy site.

Additionally, like the Mammotome elite® Biopsy System predicate device, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices use vacuum to augment target tissue acquisition and stability and are thus compatible with non-real time guidance modalities such as stereotactic guidance procedures.

The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices incorporate one-piece, combined coring and severing components. This design feature eliminates the need for a separate sharp penetration element, which enhancement also may further reduce potential trauma during placement of the cannula tip prior to initiating the tissue acquisition sequence. Like the BIP® VacuFlash Biopsy System and the Mammotome elite® Biopsy System, the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices include a detachable, radiolucent, surgical-grade plastic or stainless steel, coaxial outer tube surrounding the coring cannula which may be used to maintain access to the biopsy site for post-procedure marker placement or for intra-operative imaging.

Like the BIP® VacuFlash Biopsy System and the Sanarus Cassi™ II Rotational Core Biopsy System, the SpeedBird SBU99 Soft Tissue Biopsy Device consists of a sterile biopsy needle (probe) that is to be attached to a non-sterile, reusable biopsy handle (driver).

A direct comparison of the technical and performance characteristics of the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices to the identified predicate devices is provided below:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>SpeedBird Model SB38</th>
<th>SpeedBird Model SBU and SpeedBird Model SBU99</th>
<th>Magic™ Breast Biopsy Device</th>
<th>Sanarus Cassi™ II Rotational Core Biopsy System</th>
<th>BIP® VacuFlash Biopsy System</th>
<th>Mammotome elite® Biopsy System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance method</td>
<td>Ultrasound &amp; Stereotactic</td>
<td>Ultrasound</td>
<td>Ultrasound</td>
<td>Ultrasound</td>
<td>Ultrasound &amp; Stereotactic</td>
<td>Ultrasound &amp; Stereotactic</td>
</tr>
<tr>
<td>Cannula shaft diameter</td>
<td>10 Gauge – 14 Gauge</td>
<td>10 Gauge – 14 Gauge</td>
<td>10 Gauge</td>
<td>10 Gauge</td>
<td>10 and 14 Gauge</td>
<td>10 Gauge &amp; 13 Gauge</td>
</tr>
<tr>
<td>Method of tissue dissection</td>
<td>Rotating, forward-advancing cutting blades with integrated severing capability</td>
<td>Rotating, forward-advancing cutting blades with integrated severing capability</td>
<td>Rotating, forward-advancing round cutter with specimen severing element</td>
<td>Rotating, forward-advancing round cutter with freezing needle</td>
<td>Vacuum-assisted side trough and rotating, forward-advancing round cutter</td>
<td>Vacuum-assisted side trough and rotating, forward-advancing round cutter</td>
</tr>
<tr>
<td>Characteristics</td>
<td>SpeedBird Model SB38</td>
<td>SpeedBird Model SBU and SpeedBird Model SBU99</td>
<td>Magic™ Breast Biopsy Device</td>
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<tr>
<td><strong>Method of tissue collection</strong></td>
<td>Vacuum, through to specimen collection tube</td>
<td>Vacuum, through to specimen collection tube</td>
<td>Retention finger, transport tube, ejection pin</td>
<td>Freezing needle surrounded by outer rotating cutter</td>
<td>Side trough surrounded by outer round cutter</td>
<td>Vacuum, transport tube, ejection pin</td>
</tr>
<tr>
<td><strong>Patient contacting materials</strong></td>
<td>Stainless steel; surgical-grade plastic</td>
<td>Stainless steel; surgical-grade plastic</td>
<td>Stainless steel</td>
<td>Stainless steel; surgical-grade plastic</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
</tr>
<tr>
<td><strong>Power source</strong></td>
<td>DC Motor; Internal built-in battery power (3V batteries)</td>
<td>DC Motor; Connections for an external battery pack or a transformer power source as desired</td>
<td>DC Motor, 9V battery</td>
<td>DC motor, compressed gas, 9V battery</td>
<td>DC Motor, rechargeable battery</td>
<td>DC Motor, 110V AC</td>
</tr>
<tr>
<td><strong>Hand-held procedure?</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Single use disposable device vs. reusable device</strong></td>
<td>Single use, fully disposable</td>
<td><strong>Model SBU:</strong> Single use, fully disposable</td>
<td>Single use, fully disposable</td>
<td>Single use, disposable biopsy needle (probe); reusable handle (driver)</td>
<td>Single use, disposable biopsy needle (probe); reusable handle (driver)</td>
<td>Single use, disposable biopsy needle (probe); reusable handle (driver)</td>
</tr>
</tbody>
</table>

The minor differences between the identified predicate devices and the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices’ design features and operational principles, namely the shape of the distal-most forward cutting tip which consists of opposing oval blades rather than a single round blade, do not raise any new questions of safety or effectiveness.

**Performance Bench Testing**
The performance testing protocol was designed to reflect the similar way in which the relevant predicate devices are used clinically and the SpeedBird Model SB38 and Model SBU devices will be used in clinical procedures, specifically referring to utilizing the single insertion, multiple sampling capability. The predicate devices Magic™ Breast Biopsy Device and Mammatome elite® Biopsy System are both capable of single insertion, multiple sampling; the same as is true of the SpeedBird Model SB38 and SBU devices. Therefore, the bench testing protocol included testing the subject devices in accordance with the guidance in the instructions for use, namely, utilizing the single insertion, multi-sampling capability of the SpeedBird Model SB38 and the Model SBU devices. The SpeedBird devices were also tested in accordance with single insertion, single sample mode to replicate the BIP® VacuFlash Biopsy System predicate device and the Sanarus Cassi™ II Rotational Core Biopsy System predicate device.

The following summary of performance tests and results with bench testing were provided in support of the substantial equivalence determination.

Final-design prototypes of the SpeedBird Model SB38 and Model SBU devices were operated according to their instructions for use for penetration, coring, part-off, and tissue transport of surrogate tissues. Comparison testing was conducted where applicable.

**Study endpoints included the following:**

- Evaluate the effectiveness of tissue penetration, tissue coring, tissue sample part-off, and tissue transport, using surrogate models representing a wide variety of tissue densities as would be encountered in clinical biopsy procedures.
- Measure the force of tissue penetration.
- Evaluate sample acquisition for adequacy of providing tissue samples for histopathological evaluation.
- Evaluate effectiveness of the tissue transport mechanisms, including vacuum, fluid flush, and the transport pathway itself, for successful collection of tissue sample cores into the specimen collection tube.
- Evaluate the condition of the needle tip after each tissue sampling pass.
- Evaluate the proper functioning of the driving motor size, gear power train components, driving motor controls, and power source for motor during all penetration passes through surrogate tissues.

**Test Results**

- In both single insertion, single sample mode (to reflect use of the SpeedBird devices in comparison to the single insertion, single sample BIP® VacuFlash Biopsy System predicate device and the Sanarus Cassi™ II Rotational Core Biopsy System predicate device) as well as the single insertion, multiple sample mode, replicating the method of use of the Magic™ Breast Biopsy Device and Mammatome elite® Biopsy System, the SpeedBird devices effectively penetrated, cored, and severed all surrogate tissue types. All coring passes obtained consistent, predictable, undistorted (by unmagnified visual inspection) composite samples that varied in length and corresponding volume based on operator manually controlled coring excursion lengths, producing full-diameter specimens (uniform diameter over the length of the specimens) which ranged in length from 19mm to 46mm, with corresponding volume measurements.
- Forces required to penetrate surrogate tissues remained low, with no significant change observed over each pass in all tissue types or as depth of penetration increased. SpeedBird devices performed substantially equivalently to the predicate devices for force of penetration in all tissue types. The SpeedBird devices’ powered tip rotation utilized for challenging tissue types resulted in substantial improvement (lowering) of forces required to penetrate to a target compared to the predicate devices.
- No tissue sampling bias was noted with either SB38 or SBU.
• SpeedBird needle tips continued to rotate throughout all powered passes in all tissue types and remained undistorted following all portions of the testing.
• Motor torque and battery power remained adequate throughout the procedures, with no requirement to exchange batteries. No significant change in needle rotation speed observed.

Conclusions

Substantial equivalence to the identified predicate devices is based on the following:

• Indications For Use: The SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices have essentially the same indications for use as the identified predicate device Sanarus Cassi™ II Rotational Core Biopsy System (K051581). The other identified predicate devices have indications for use that are a subset of the indications for use for the SpeedBird Soft Tissue Biopsy Devices and the identified predicate device Sanarus Cassi™ II Rotational Core Biopsy System (K051581).

• Technology characteristics: The device technology comparisons demonstrate that the design features, operational principles, patient contacting material composition, energy source, and other technological characteristics of the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are substantially equivalent to the identified predicate devices, with minor differences that do not raise any new questions of safety or effectiveness.

• Performance testing: Performance testing of the SpeedBird Soft Tissue Biopsy Devices demonstrates that the SpeedBird devices perform substantially equivalently to the identified predicate devices, and that the features of the SpeedBird devices do not raise any new issues of safety and effectiveness.

The data provided in the 510(k) submission together support the determination that the SpeedBird Model SB38, Model SBU, and Model SBU99 Soft Tissue Biopsy Devices are as safe, as effective, and perform substantially equivalently to the identified predicate devices.