Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address: CIVCO Medical Instruments Co., Inc. d/b/a CIVCO Medical Solutions
102 First Street South
Kalona, Iowa 52247

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Date Summary Prepared: April 22, 2013

Trade Names:
EX3 Stepper™, Classic Stepper, Multi-Purpose Workstation™ Stepper;
Micro-Touch™, Micro-Touch™ LP, Multi-Purpose Workstation™, Multi-Purpose Workstation™ LP;
Disposable Template Grid
(These devices are marketed as part of the AccuCARE™ product line)

Common Names:
Stepping Unit Stabilizer
Disposable Template Grid

Classification Names:

Classification Numbers:
Class II under 21 CFR 892.1570
Class I under 21 CFR 892.5650
Class II under 21 CFR 892.5700

Review Panels:
Radiology

Product Codes:
ITX, IWJ, & JAQ

B. Predicate Devices

The subject devices are substantially equivalent to the predicate devices included in the following 510(k)s:

<table>
<thead>
<tr>
<th>Predicate Devices</th>
<th>Mfg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>K972672: Brachystepper Stepping Unit, Brachystand Support and Manual Adjustment Accessory</td>
<td>Barzelli-Whitmore Maroon Bells, Inc. (acquired by CIVCO Medical Instruments Co., Inc.)</td>
</tr>
</tbody>
</table>

Note: The Brachystepper Needle Guide Template component in this 510(k) is not being used as a predicate.
The subject devices, with the exception of the EX3 Stepper, have been marketed for many years under K972672 and K981873. The purpose of this 510(k) is to modify the intended use of these devices to include cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. These additional applications fall within the indications for use and the literature demonstrates that these devices have been safely and effectively used for many years in these applications. These changes do not raise new issues of safety and effectiveness because the system continues to be used for positioning in males with suspected or diagnosed prostate cancer. These changes do not impact or modify the therapy and CIVCO did not modify the design of these devices to enable use in these additional applications.

The second purpose of this 510(k) is to provide a premarket notification for the EX3 Stepper. The EX3 Stepper is similar to the predicate in that it holds an ultrasound imaging probe and facilitates manual linear and rotational positioning of the probe. The EX3 Stepper differs from the predicate in that it offers continuous (free) longitudinal movement and contains encoder components that are powered via a USB-hub. Firmware in the encoders report position and this position is read by treatment planning software marketed by other companies. This position reporting function has been added to the EX3 intended use. Verification and validation testing confirmed that these changes in design do not raise new questions of safety and effectiveness.

C. Device Description

Stepping Unit
The Stepping Unit holds an ultrasound imaging probe and facilitates manual linear and rotational positioning of the probe. The Stepping Unit consists of a Cradle designed to hold a specific ultrasound probe and a Carriage that moves longitudinally along the Stepping Unit. A Grid Platform connected at one end of the Stepper provides support for the Disposable Template Grid. The Stepping Unit connects to the Stabilizer.

Stabilizer
The Stabilizer provides a base for the Stepping Unit and offers fixation and support during insertion and final placement of the ultrasound imaging probe. On certain models, a fine tune mechanism is used to micro-adjust the probe or instrument to the ideal orientation. The Stabilizer mounts to an operating room table or is supported by a floor stand.

Disposable Template Grid
The Disposable Template Grid is a single-use, sterile grid that consists of rows and columns of holes (channels) spaced 5mm apart. These channels are labeled and provide placement of needles in predefined areas of the prostate.
The following part numbers are included in this 510(k):

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Trade Name</th>
<th>Part No.</th>
<th>Device Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stepping Unit</td>
<td>EX3 Stepper™</td>
<td>609-004</td>
<td>EX3 Stepper for use with Best Sonalis transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>612-228</td>
<td>EX3 Stepper for use with Acuson ER7B transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>614-119</td>
<td>EX3 Stepper for use with Aloka UST-672-5/7.5 transducers</td>
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<tr>
<td></td>
<td></td>
<td>620-119</td>
<td>EX3 Stepper for use with B-K Medical 8658 (8558) transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>642-443</td>
<td>EX3 Stepper for use with GE Healthcare ERB transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>644-081</td>
<td>EX3 Stepper for use with Hitachi EUP-U533 transducers</td>
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<tr>
<td></td>
<td></td>
<td>676-177</td>
<td>EX3 Stepper for use with Siemens Endo P-II transducers</td>
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<tr>
<td></td>
<td></td>
<td>683-003</td>
<td>EX3 Stepper for use with Terason 8B4S transducers</td>
</tr>
<tr>
<td>Classic Stepper</td>
<td>614-092</td>
<td></td>
<td>Classic Stepper for use with Aloka UST-672-5/7.5 transducers</td>
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<tr>
<td></td>
<td>644-064</td>
<td></td>
<td>Classic Stepper for use with Hitachi EUP-U533 transducers</td>
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<tr>
<td></td>
<td>612-225</td>
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<td>Classic Stepper for use with Acuson ER7B transducers</td>
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<tr>
<td></td>
<td>642-316</td>
<td></td>
<td>Classic Stepper for use with GE Healthcare ERB transducers</td>
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<tr>
<td></td>
<td>620-089</td>
<td></td>
<td>Classic Stepper for use with B-K Medical 8658 (8558) transducers</td>
</tr>
<tr>
<td></td>
<td>676-114</td>
<td></td>
<td>Classic Stepper for use with Siemens Endo-P II transducers</td>
</tr>
<tr>
<td></td>
<td>609-001</td>
<td></td>
<td>Classic Stepper for use with Best Sonalis transducers</td>
</tr>
<tr>
<td>Multi-Purpose Workstation™ Stepper</td>
<td>614-098</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with Aloka UST-672-5/7.5</td>
</tr>
<tr>
<td></td>
<td>642-334</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with GE Healthcare ERB</td>
</tr>
<tr>
<td></td>
<td>644-066</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with Hitachi EUP-U533</td>
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<tr>
<td></td>
<td>676-121</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with Siemens Endo-P II</td>
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<tr>
<td></td>
<td>620-094</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with B-K Medical 8658 (8558), 8808</td>
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<tr>
<td></td>
<td>620-113</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with B-K Medical 8808e, 8818</td>
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<tr>
<td></td>
<td>620-117</td>
<td></td>
<td>Multi-Purpose Workstation Stepper for use with B-K Medical 8848</td>
</tr>
<tr>
<td>Stabilizer</td>
<td>Micro-Touch™</td>
<td>610-911</td>
<td>Micro-Touch (Dual-Sided Table Mount)</td>
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<tr>
<td></td>
<td></td>
<td>610-911S</td>
<td>Micro-Touch Transportation Stand</td>
</tr>
</tbody>
</table>
D. Indications for Use

This device is indicated for use in adult males with known or suspected prostate cancer.

E. Intended Use

System Intended Use:
Intended for use in ultrasonic procedures related to brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Component-specific Intended Uses:
Stepping Unit (Multi-Purpose Workstation Stepper, Classic Stepper): Holding and manipulating ultrasound imaging probes during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement procedures (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Stepping Unit (EX3 Stepper): Holding and manipulating ultrasound imaging probes, and reporting position, during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement procedures (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.

Stabilizer: Provides fixation, support and manipulation of transrectal ultrasound imaging probes during insertion and final placement.
Disposable Template Grid: Accepting and guiding needles up to 1.3 mm (18 gauge) in diameter and providing coordinates as an aid to needle loading and positioning during radioactive seed implantation, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement.

F. Technological Characteristics

Stepping Unit
Both the subject and predicate Stepping Units are designed to hold and manipulate ultrasound imaging probes during prostate procedures and enable manual linear and rotational positioning of the probe. The subject and predicate Stepping Units consist of a Cradle designed to hold and rotate an ultrasound probe, a Carriage that moves longitudinally along the Stepping Unit, and a Grid Platform connected at one end of the Stepper to attach the Disposable Template Grid. The proposed EX3 Stepper differs from the predicate in that it offers continuous (free) longitudinal movement of the Carriage and contains encoder components that are powered via a USB-hub. Firmware in the encoders report position and this position is read by treatment planning software marketed by other companies.

Stabilizer
Both the subject and predicate Stabilizers are designed to serve as a base for the Stepping Unit. The subject and predicate Stabilizers offer fixation and support during insertion and final placement of the ultrasound imaging probe. Whereas the predicate device only mounted on a floor stand, several of the subject Stabilizers can be mounted to an operating table. The fine tune adjustment mechanism on the predicate device is incorporated in the Micro-Touch Stabilizers, but not the Multi-Purpose Workstation Stabilizers.

Disposable Template Grid
Both the subject and predicate Disposable Template Grids are single-use, sterile grids that consist of rows and columns of holes (channels) spaced 5mm apart. These channels are labeled and provide placement of needles in predefined areas of the prostate. The subject device is sterilized via EtO gas, whereas the predicate device was sterilized by gamma irradiation. Also, the subject device is made of ABS while the predicate device was constructed from polycarbonate. The subject device is labeled with a 3 year expiration date.

G. Literature Review, Non-Clinical Performance Testing, and Conclusions

A literature review was conducted to support the modification of the intended use to include cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. The literature demonstrates that these devices have been safely and effectively used in cryotherapy, transperineal template-guided biopsy, and fiducial marker placement. No design changes were made to enable use of the devices in these additional applications.
Additionally, non-clinical performance testing was conducted on the EX3 Stepper including verification testing on the following characteristics:

- Stepping Unit is able to provide continuous (free) longitudinal movement
- Encoders correctly report longitudinal and rotational motion of Stepping Unit
- Stepping Unit meets electrical safety requirements of IEC 60601-1 and IEC 60601-1-1

Validation was also conducted to confirm the device remains safe and effective for its intended use and included testing with treatment planning software.

All testing confirmed that the EX3 Stepper is substantially equivalent to the predicate device in regards to safety and effectiveness and the new design features have not diminished the safety and effectiveness of the device.
September 17, 2013

CIVCO Medical Instruments Co., Inc.  
d/b/a CIVCO Medical Solutions  
% Ms. Amanda Stahle  
Regulatory Affairs Specialist  
102 First Street South  
KALONA IA 52247

Re: K131161  
Trade/Device Name: Ex3 Stepper™; Classic Stepper, Multi-Purpose Workstation™ Stepper;  
Micro-Touch™ Micro-Touch™ LP, Multi-Purpose Workstation™,  
Multi-Purpose Workstation™ LP; and Disposable Template Grid

Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: ITX, IWJ, JAQ  
Dated: August 28, 2013  
Received: August 29, 2013

Dear Ms. Stahle:

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,

[Signature]

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K131161

Device Name: Stepping Unit
Stabilizer
Disposable Template Grid

Indications for Use: This device is indicated for use in adult males with known or suspected prostate cancer.

Prescription Use ___ X ___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K131161