Section 6 – 510(k) SUMMARY

510(k) Summary As Required by 21 CFR 807.92 (c)

Owner: Sentra Medical Devices LLC
2831 Woodmont Dr. W.
Canton, MI 48188

Contact Person: Karthik Narayan
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Date of Summary: 04-30-2006

Device Information

Trade Name: True Pulse Invasive Blood Pressure Monitoring Kit
Common Name: Invasive Blood Pressure Monitoring Kits
Classification Name: Transducer, Blood-pressure, Extravascular
C F R Section: 870.2850
Product Code: DRS

Predicate Device

Edwards Lifesciences Pressure Monitoring Kit with TruWave Disposable Pressure Transducer has been chosen as the predicate device for this pre-market application. The filing of the 510(k) associated with this predicate device is K8329Q7, filed by American Pharmaseal, a Baxter Edwards company, for a blood pressure transducer including a continuous flush device, marketed by Edwards Lifesciences.

Description of the Device

Sentra's 'TruePulse' Invasive Pressure Monitoring Kits are indicated for use in physiological, invasive pressure measurement, and are for use with patients requiring intravascular pressure monitoring.

The True Pulse Disposable Blood Pressure Kit from Sentra Medical Devices LLC consists of an Arterial extension line (available in various standard lengths) is attached via a luer connection to the catheter that is inserted into the patient, (the male portion of the lumen is a part of the kit and the female portion of the lumen is a part of the catheter, the catheter is not a part of this device) a stopcock, a monitoring line, to another stopcock, a transducer, a continuous flow flush device, and an IV set all connected by standard luer connections.

The device functions by continuously monitoring changes in blood pressure from the function of the heart. The pressure waves generated in the heart are transmitted through the vascular system, to the catheter and then through the saline fluid - filled tubing to a transducer. Upon reaching the transducer, pressure waves from the fluid pathway depress a diaphragm, changing the resistance to the flow of current through a circuit. The change in resistance produces an electrical event that creates a signal that is then transmitted to a monitor through a cable and displaying pressure reading and a waveform on a monitor. (The catheter and monitor are not parts of this kit).

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### Intended Use

Usually patients who require this type of monitoring have one of two major common factors, failure of the heart to pump effectively or a major disturbance of the circulatory system. The heart failure can be the result of several diseases such as acute myocardial infarction, long-standing valve disease, and cardio-myopathy. Major disturbances of the circulatory system may be major blood loss due to trauma, major surgery, or excessive fluid shifts within the body.

### Comparison of the True Pulse Disposable Blood Pressure Kit to the predicate device.

The True Pulse Disposable Blood Pressure Kit is being compared to the Edwards Life sciences Pressure Monitoring Kit with TruWave Disposable Pressure Transducer (Ref: PX260). Components of each kit are described in the table below.

#### Usage comparison

<table>
<thead>
<tr>
<th>Item</th>
<th>Sentra’s True Pulse</th>
<th>Edwards TruWave</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic description</strong></td>
<td>Single use transducer kit</td>
<td>Single use transducer kit</td>
<td>Similar</td>
</tr>
<tr>
<td><strong>Target usage</strong></td>
<td>Patients requiring invasive pressure measurement and monitoring</td>
<td>Patients requiring invasive pressure measurement and monitoring</td>
<td>Similar usage</td>
</tr>
<tr>
<td><strong>Where used</strong></td>
<td>In Hospitals, by trained health care personnel</td>
<td>In Hospitals, by trained health care personnel</td>
<td>Similar</td>
</tr>
<tr>
<td><strong>Sterilization</strong></td>
<td>ETO sterile</td>
<td>ETO sterile</td>
<td>Similar type of sterilization</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Coiled and taped tubes in a Tyvek and Mylar pack, heat sealed peel-open package</td>
<td>Coiled and taped tubes in a Tyvek and Mylar pack, heat sealed peel-open package</td>
<td>Similar type of packaging</td>
</tr>
</tbody>
</table>

#### Technological Characteristics comparison

<table>
<thead>
<tr>
<th>Kit Components</th>
<th>Sentra’s True Pulse</th>
<th>Edwards TruWave</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arterial Extension Line</strong></td>
<td>Extruded PVC tube bonded to Luers at both ends</td>
<td>Extruded PVC tube bonded to Luers at both ends</td>
<td>Similar design &amp; construction, similar functions</td>
</tr>
<tr>
<td><strong>Stopcock for fluids collection</strong></td>
<td>Molded housing with handle rotating a core, Luer ends, cap</td>
<td>Molded housing with handle rotating a core, Luer ends, cap</td>
<td>Similar design &amp; construction, similar functions</td>
</tr>
<tr>
<td><strong>Monitoring Line</strong></td>
<td>Extruded PVC tube bonded to Luers at both ends</td>
<td>Extruded PVC tube bonded to Luers at both ends</td>
<td>Similar design &amp; construction, similar functions</td>
</tr>
<tr>
<td><strong>Stopcock for zeroing</strong></td>
<td>Molded housing with handle rotating a core, one Luer end, non-vented cap</td>
<td>Molded housing with handle rotating a core, Luer ends, vented cap</td>
<td>Similar design &amp; construction, similar functions</td>
</tr>
<tr>
<td></td>
<td>1986. Interchangeability and performance of resistive bridge type blood pressure transducers. Stand alone transducer, injection molded housing, Pole or patient arm mounted, wheat Stone bridge connector, sensor element isolated by gel, Luer ends.</td>
<td>Stand alone transducer, injection molded housing, Pole or patient arm mounted, wheat Stone bridge connector, sensor element isolated by gel, Luer ends.</td>
<td>Standards that Edwards transducer meets, as outlined in the comparison column.</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Flush Device</strong></td>
<td>Injection molded housing, Squeeze handle changes flow rate, Luer connections, stand alone flush device</td>
<td>Injection molded housing, pulling tab changes flow rate, integrated in transducer housing</td>
<td>Differences in overall construction, similar function</td>
</tr>
<tr>
<td><strong>IV Set</strong></td>
<td>Molded spike, drip chamber, tube bonded to Luer, roller clamps</td>
<td>Molded spike, drip chamber, tube bonded to Luer, roller clamp</td>
<td>Similar construction, function</td>
</tr>
</tbody>
</table>

Edwards TruWave transducer housing has integrated in it, a stop-cock and flush device while in Sentra’s design these items are stand-alone. The reason for integration in Edwards design is cost savings and the two kits were found to be substantially equivalent in function. The two kits were found to be substantially equivalent based on the following functional tests performed on 4 samples each of the two devices:

- Luer inspection *per ISO 594*
- De-bubbling and leak
- Output flow
- Transducer Zero setting
- Square wave response
- Prolonged exposure dwell with 300 mmHg saline pressure, and pressure accuracy during and after prolonged exposure
- Volume of kit CC

This bench testing of the Sentra Kits as compared to the Edward’s Kits showed that the Sentra Kit served the same functions with the same degree of safety as the Edward’s Kits.

**Design**

Specifications for components and packaging including materials used, functions required were developed. Kits were built and sterilized with production intent methods and processes. These kits were then used for functional and predicate device comparison testing.

Sentra has utilized Failure Modes and Effects Analysis to estimate and mitigate risks.

Materials for the kits components were chosen with careful analysis of material properties. Detailed material properties, and the list of materials used are discussed in the Sentra’s 510(k) sections and exhibits.

Drawings of the components, assembly have been provided in the 510(k).
Sentra will market standard variants of the base design. The variation is only in the presence or absence of some of the components, variations in lengths of the tubes, while utilizing the same materials and base design verified in testing. A matrix showing these variants is discussed in the 510(k).

Testing and verification

The Sentra Kit has passed sterilization tests, bio-compatibility requirements, and product performance standards set forth by Sentra as proven in bench tests. International standards have been adopted in several areas, deemed important. The tests conducted, flow, procedures, acceptance criteria and results are discussed elsewhere in the 510(k).

All tests were designed in a test flow, with detailed test procedures and tests were executed in 2 legs, one was for functional verification of the kits and second for proof of substantial equivalence.

The transducer complies with the industry consensus standard AAMI BP22: 1995 R 2001 tested by our transducer supplier. Results are provided in the 510(k) Exhibit 1.

Detailed discussion and results on all of these topics are available in Sentra’s 510(k) sections and exhibits.
Sentra Medical Devices, LLC  
c/o Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25th Street NW  
Buffalo, MN 55313

Re: K062342  
Trade Name: Sentra True Pulse Invasive Pressure Monitoring Kit  
Regulation Number: 21 CFR 870.2850  
Regulation Name: Extravascular Blood Pressure Transducer  
Regulatory Class: Class II (two)  
Product Code: DRS  
Dated: September 9, 2006  
Received: September 11, 2006

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

[Signature]

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): Not issued yet.

Device Name: Sentra True Pulse Invasive Pressure Monitoring Kit

Indications For Use:

Sentra's 'TruePulse' Invasive Pressure Monitoring Kits are indicated for use in physiological, invasive pressure measurement, and are for use with patients requiring intravascular pressure monitoring.

Prescription Use: Yes AND/OR Over-The-Counter Use: No

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular Devices
510(k) Number

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