SECTION 9: 510(K) SUMMARY

1. Summary Preparation Date: June 12, 2007

2. 510(k) Applicant Information:
   - Name: Midmark Diagnostics Group
   - Address:
     3300 Fujita Street
     Torrance, CA 90505
     USA
   - FDA Establishment registration Number: 2081230
   - Contact Name: Tony Capparelli, Director of Product Development
   - Phone Number: 310-257-7217
   - Fax Number: 310-530-1421

3. Device Names and Designations
   - Proprietary Name: IQmark® Vital Signs Monitor
   - Module Configuration:
     | NIBP* | Temp | SpO₂ |
     |-------|------|------|
     | X     | X    | X    |
     * Noninvasive Blood Pressure
   - Overall Device Common/Usual Name: Vital Signs Monitor
   - Overall Device Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection)

4. Product Codes, Regulations, Class, and Panels:

<table>
<thead>
<tr>
<th>Component</th>
<th>Product Code</th>
<th>Regulation Number</th>
<th>Class</th>
<th>Regulation Medical Specialty</th>
<th>Review Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Device</td>
<td>MWi</td>
<td>870.2300</td>
<td>2</td>
<td>Cardiovascular</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>NIBP</td>
<td>DXN</td>
<td>870.1130</td>
<td>2</td>
<td>Cardiovascular</td>
<td>Cardiovascular</td>
</tr>
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<td>Oximeter</td>
<td>DQA</td>
<td>870.2700</td>
<td>2</td>
<td>Cardiovascular</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Thermometer</td>
<td>FLL</td>
<td>880.2910</td>
<td>2</td>
<td>Gen. Hospital</td>
<td>Gen. Hospital</td>
</tr>
</tbody>
</table>

4. Substantial Equivalency: The Midmark Diagnostics IQmark® Vital Signs Monitor is substantially equivalent to these predicate devices:
   - CAS Medical 740 Series Vital Signs Monitor (K033048)
   - Welch Allyn Vital Signs Monitor (K053027)
   - and IVAC Model 2080 Electronic Thermometer (K860436)

Like the CAS Medical 740 Series Vital Signs Monitor, the IQmark® Vital Signs Monitor is for monitoring of noninvasive blood pressure, oxygen saturation, pulse rate and temperature of adult, pediatric, and neonatal populations under care of health care professionals in general medical locations, hospitals, and alternative care environments.
The following tables compare the physical and performance characteristics of the proposed device to the predicate devices. Table 1 compares the IQmark® VSM to the CAS Medical 740 Series Vital Signs Monitor (K033048). Table 2 compares the IQmark VSM temperature module to the IVAC Model 2080 Electronic Thermometer (K860436) and Welch Allyn VSM 300 (K053027).

Table 1: Physical and Performance Characteristics of IQmark® Vital Signs Monitor To CAS Medical 740 Series Vital Signs Monitor

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CAS Medical 740 Series Vital Signs Monitor (K033048)</th>
<th>IQmark® Vital Signs Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available module configurations</td>
<td>NIBP/Oximeter/Temperature</td>
<td>NIBP/Oximeter/Temperature</td>
</tr>
<tr>
<td>Overall operational modes</td>
<td>Adult, neonatal, power-on self-test, auto off, off and history</td>
<td>Adult, neonatal, power-on self-test, auto off, off and history</td>
</tr>
<tr>
<td>NIBP modes</td>
<td>Manual, automatic, and stat</td>
<td>Manual, automatic, and stat</td>
</tr>
<tr>
<td>NIBP module operating principle</td>
<td>Oscillometric method employing a stepwise pressure deflation technique</td>
<td>Oscillometric method employing a stepwise pressure deflation technique</td>
</tr>
<tr>
<td>NIBP accuracy</td>
<td>+/- 5 mmHg, standard deviation no greater than 8 mmHg</td>
<td>+/- 5 mmHg, standard deviation no greater than 8 mmHg</td>
</tr>
<tr>
<td>NIBP cuff types</td>
<td>reusable and disposable</td>
<td>reusable and disposable</td>
</tr>
<tr>
<td>NIBP cuff sizes</td>
<td>adult, infant, and neonatal</td>
<td>adult, infant, and neonatal</td>
</tr>
<tr>
<td>SpO2 modes</td>
<td>Continuous monitoring and off</td>
<td>Continuous monitoring and off</td>
</tr>
<tr>
<td>SpO2 reading range (%)</td>
<td>0 - 100</td>
<td>0 - 100</td>
</tr>
<tr>
<td>SpO2 accuracy</td>
<td>adult: 70-100%: ± 2 counts, neonate: 70-100%: ± 3 counts</td>
<td>adult: 70-100%: ± 2 counts, neonate: 70-100%: ± 3 counts</td>
</tr>
<tr>
<td>SpO2 sensor types</td>
<td>Reusable and disposable</td>
<td>Reusable and disposable</td>
</tr>
<tr>
<td>SpO2 sensor sizes</td>
<td>adult, infant, and neonatal</td>
<td>Adult, infant, and neonatal</td>
</tr>
<tr>
<td>Alarm conditions</td>
<td>high and low alarms: pulse rate, systolic &amp; diastolic BP, MAP, &amp; SpO2</td>
<td>high and low alarms: pulse rate, systolic &amp; diastolic BP, MAP, &amp; SpO2</td>
</tr>
<tr>
<td>Power supply type</td>
<td>100-240 VAC (50-60 Hz) or charged NiMH battery</td>
<td>100-240 VAC (50-60 Hz) or charged sealed lead acid battery</td>
</tr>
</tbody>
</table>
Table 2: Physical and Performance Characteristics of IQmark® Vital Signs Monitor To IVAC Model 2080 Electronic Thermometer and Welch Allyn VSM 300

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IVAC Model 2080 Electronic Thermometer (K860436)</th>
<th>Welch Allyn Vital Signs Monitor (K053027)</th>
<th>IQmark® Vital Signs Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermometer type</td>
<td>Electronic, thermistor</td>
<td>Electronic, thermistor</td>
<td>Electronic, thermistor</td>
</tr>
<tr>
<td>Temperature reading range</td>
<td>Continuous mode: 26.7 - 42.2 °C (80 - 108.0 °F)</td>
<td>28.9 - 42.2 °C (84.0 - 108.0 °F)</td>
<td>28.9 - 42.2 °C (84.0 - 108.0 °F)</td>
</tr>
<tr>
<td></td>
<td>Predictive mode: 31.6 - 42.2 °C (88.9 - 108.0 °F)</td>
<td>Not specified</td>
<td>35.0 - 41.1 °C (95.0 - 106.0 °F)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Continuous mode: ± 0.1 °C (± 0.2 °F), meet or exceeds ASTM E1112-00 requirements</td>
<td>± 0.1 °C (± 0.2 °F), meet or exceeds ASTM E1112-00 requirements</td>
<td>± 0.1 °C (± 0.2 °F), meet or exceeds ASTM E1112-00 requirements</td>
</tr>
<tr>
<td></td>
<td>Predictive mode: +0.6 °C (+1.0 °F)</td>
<td>Not specified</td>
<td>+0.6 °C (+1.0 °F)</td>
</tr>
</tbody>
</table>

The physical and performance characteristics of the IQmark® Vital Signs Monitor are very similar to those of the predicate device with a few non-significant differences in technological characteristics. The results of extensive software and hardware verification and validation testing, safety, and performance testing demonstrate that the different technological characteristics used in the IQmark® Vital Signs Monitor pose no new issues of safety and effectiveness and therefore is substantially equivalent to the predicate devices.

5. Performance Testing Summary:
The IQmark VSM has been tested for safety and efficacy and found to be in conformance with the following safety standards and performance standards applicable to blood pressure, SpO₂, and temperature modules:

EN 60601-1-2
IEC 60601-1-4
EN 60601-1-8
EN 9919
IEC 60601-1
ANSI/AAMI SP10
ASTM E1112

Additionally, the operational and performance specifications for each measurement module and for the IQmark Vital Signs Monitor as a system has been successfully verified and validated. Results demonstrate that the IQmark® Vital Signs Monitor poses no new issues of safety and effectiveness and therefore is substantially equivalent to the predicate devices.

The IQmark® Vital Signs Monitor Risk Analysis document identifies potential failure / hazard combinations associated with the use of the VSM, and mitigations to reduce patient risks. The document con-
cludes that the IQmark® Vital Signs Monitor is a safe device that poses no unacceptable risks to the pa-
tient.

6. Intended Use, Indications for Use, & Environment:

**Intended Use and Indications:** The Midmark Diagnostics IQmark® Vital Signs Monitor is intended to be
used by clinicians and medically qualified personnel for monitoring adult, pediatric and neonatal patients
for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriole hemo-
globin (SpO₂), and body temperature. In adults and pediatric patients, temperature is monitored orally,
rectally, or at axillary sites. In neonates (to 1 month) temperature is monitored at axillary sites only.

**Intended Environment:** The most likely locations for patients to be monitored are general medical loca-
tions, hospitals, and alternative care environments.

**Contraindications:** The IQmark® Vital Signs Monitor may not be suitable for use on patients under the
following conditions:

a. Oral and Rectal temperature measurements are contraindicated for neonatal use.
b. Reusable SpO₂ sensors are contraindicated for prolonged use. The sensors must be removed
every 4 hours and, if indicated by circulatory condition and skin integrity, reapplied to a dif-
ferent monitoring site.
c. Disposable SpO₂ sensors are contraindicated for patients that exhibit allergic reactions to ad-
hesive tape. The sensors must be removed every 8 hours and, if indicated by circulatory con-
dition and skin integrity, reapplied to a different monitoring site.

**Complications:** Except for temperature measurement, the IQmark® Vital Signs Monitor is a noninvasive
device. The device is safe in construction and performance. This has been confirmed by the successful
completion of Verification and Validation Testing, Biocompatibility Confirmation, and Risk Analysis.

Following are some possible complications:

a. Prolonged use of the adhesive tape used to attached disposable SpO₂ sensors may cause aller-
gic reactions in some patients.
b. Prolonged use of reusable or disposable SpO₂ sensors may cut-off circulation in some patients.
c. Repeated application and use of temperature probe covers to the same tissue area may cause
mild irritation at tissue site.
d. Failure to follow directions for rectal probe insertion could result in bowel perforation, espe-
cially in young children.

7. General Device Description: The Midmark Diagnostics IQmark® Vital Signs Monitor consists of the
following three individual measurement Modules:

a. Noninvasive blood pressure (NIBP)
b. Pulse Oximeter
c. Temperature

In the Automatic or STAT Modes of operation, the NIBP Module automatically inflates an occluding cuff
placed around the patient’s arm or leg. It uses the oscillometric measurement technique to measure and
record the patient’s systolic and diastolic pressure as well as pulse rate. From these measurements the
IQmark VSM also calculates the mean arterial blood pressure (MAP). Measurement results along with
operator prompts and error messages are indicated on the front panel display. The frequency of NIBP determination can be selected by the operator at fixed times between one and ninety minutes. The Manual Mode of operation also covers a variety of clinical uses. A variety of reusable and disposable cuff types and sizes is available for adult, pediatric, and neonatal applications. The NIBP Module requires routine calibration and maintenance.

The Pulse Oximeter Module measures and records the patient's arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through tissue (SpO₂). Changes in absorption caused by pulsations of blood in the patient's vascular bed are used to determine arterial oxygen saturation and pulse rate. Oxygen saturation and heart rate are indicated on the front panel display. A bar graph display gives the user a pulse-by-pulse visual indication of waveform signal quality. An audible indicator can be enabled which automatically generates a sound each time the SpO₂ sensor detects a pulse. The IQmark VSM utilizes the Masimo Set® oximeter. A variety of reusable and disposable sensor types and sizes is available for adult, pediatric and neonatal applications. These oximeter does not require routine calibration or maintenance.

The Temperature Module measures and records a patient's temperature in either the Predictive or Continuous Mode of operation using either oral (also used for axillary) or rectal probes. In the Predictive Mode, the thermometer's software predicts body temperature in about 15 seconds for oral and axillary temperatures. The IQmark VSM Temperature Module does not support Predictive Mode measurements for the rectal temperature probe. The default mode used by the IQmark VSM for oral temperature determinations is the Predictive Mode. The Continuous Mode is usually used for longer-term monitoring or when difficult situations prevent accurate patient temperature measurement in the Predictive Mode. Temperature probe covers are required and are available for the oral/axillary and rectal probes. The Temperature Module requires routine calibration and maintenance.

When the Alarm Setting Mode is activated, high and low alarm limits can be set (within specification and safety limits) for heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO₂.

8. Device Materials Biocompatibility: All blood pressure cuff, SpO₂ sensor, and temperature probe cover materials that come into contact with the patient's body tissue are in full compliance with all the applicable FDA biocompatibility requirements.
Midmark Diagnostics Group
c/o Mr. Tony Capparelli
Director of Product Development
3300 Fujita Street
Torrance, CA 90505

Re: K072516
Iqmark® Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 3, 2007
Received: October 4, 2007

Dear Mr. Capparelli:

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,

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

Enclosure
SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ____________________________

Device Name: Midmark Diagnostics IQmark® Vital Signs Monitor

Indications For Use:

The Midmark Diagnostics IQmark® Vital Signs Monitor is intended to be used by clinicians and medically qualified personnel for monitoring adult, pediatric and neonatal patients for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO₂), and body temperature. In adults and pediatric patients, temperature is monitored orally, rectally, or at axillary sites. In neonates (to 1 month) temperature is monitored at axillary sites only.

The most likely locations for patients to be monitored are general medical locations, hospitals, and alternative care environments.

Prescription Use ☒ AND/OR Over-The-Counter Use ___
(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Cf)
Division of Cardiovascular Devices
510(k) Number K072514

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