## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

### I. GENERAL INFORMATION

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|---|---|
| Device Generic Name: | continuous glucose sensor |
| Device Trade Name: | STS®-7 Continuous Glucose Monitoring System |
| Applicant's Name and Address: | DexCom, Inc.<br>5555 Oberlin Drive<br>San Diego, CA 92121 |
| Date of Panel Recommendation: | None |
| Premarket Approval Application (PMA) Number: | P050012/S001 |
| Date of Notice of Approval to Applicant: | May 31, 2007 |

### II. INDICATIONS FOR USE

The STS-7 Continuous Glucose Monitoring System (STS-7 System) is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults (age 18 and older) with diabetes. The STS-7 System is intended for use by patients at home and in health care facilities. The device is for prescription use only.

The STS-7 Continuous Glucose Monitoring System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The STS-7 Continuous Glucose Monitoring System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the STS-7 System results should be based on the trends and patterns seen with several sequential readings over time.

### III. CONTRAINDICATIONS

The STS-7 System must be removed prior to Magnetic Resonance Imaging (MRI).

Use of acetaminophen-containing medications while the STS-7 Sensor is inserted may affect the performance of the device.

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## IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the STS-7 Continuous Glucose Monitoring Labeling.

## V. DEVICE DESCRIPTION

The DexCom STS-7 Continuous Glucose Monitoring System (STS-7 System) is an externally worn glucose Sensor that continuously tracks and reports glucose values and trending information in real-time for up to 168 hours (7 full days). The STS-7 System is designed to provide continuous measurement of glucose concentrations over a 40-400 mg/dL range, and consists of 3 principle components; the STS-7 Sensor (with Applicator), the STS Transmitter, and the STS Receiver.

Once the STS-7 Sensor is inserted and the STS Transmitter is installed, the STS-7 Sensor requires a 2-hour Start-up Period for Sensor equilibration. At the end of this period, the Receiver prompts the user to calibrate the System with two blood glucose fingersticks taken with the OneTouch® Ultra® Blood Glucose meter. The user then uploads the blood glucose values taken directly to the Receiver using a connection cable[1]. After calibration, the STS-7 System provides a glucose reading and updated 1-hour, 3-hour, and 9-hour glucose trend information for viewing every 5 minutes. The STS-7 System also has programmable High and Low Glucose Alerts and a non-changeable Low Glucose ALARM set at 55 mg/dL.

### A. Description of System Components

1. STS-7 Sensor

The STS-7 Sensor is a sterile device, inserted into the abdominal subcutaneous tissue using an introducer mechanism, the STS Applicator. The STS Applicator is adhered to the surface of the skin and facilitates the introduction of the 26-gauge introducer needle housed within the STS Applicator. After deployment of the introducer needle, the needle is retracted back into the STS Applicator and the Sensor remains beneath the surface of the skin, held in place by the STS Pod (Transmitter housing). The STS-7 Sensor is a glucose oxidase-based enzyme probe.

2. STS Transmitter

Once the Transmitter is installed in the STS Pod the Transmitter measures the glucose signal and transmits the glucose information to the STS Receiver. The STS Transmitter consists of a Printed Circuit Board (PCB) with a signal filtering microchip, an antenna, and two 1.5-volt batteries, all of which are housed in a polymer-based material. The STS Transmitter contains the circuitry used to measure the electrical current signal from the STS Glucose Sensor, and the RF circuitry used to transmit the Sensor data. The antenna is used to transmit the Sensor data at 5-minute intervals to the STS Receiver via RF. The RF link that is established between the STS Transmitter and STS Receiver is for transfer of glucose data only. The STS-7 Sensor/Transmitter Pod are water resistant and no occlusive dressing is necessary for showering or bathing.

3. STS Receiver

The Receiver is a pager-like device with a re-chargeable battery. Users must keep the Receiver within 5 feet of the Transmitter to ensure Sensor-Receiver transmission.

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[1] The STS-7 System is currently only compatible with the OneTouch Ultra Blood Glucose Meter.

Users must enter a 5-digit, alphanumeric Transmitter Serial Number into the STS Receiver to establish secure, wireless communication between the Receiver and Transmitter.

Once STS Receiver-Transmitter communication is established, the STS Receiver captures, stores, and converts the Sensor signal to glucose concentrations using its internally programmed algorithms after calibration. The STS Receiver is calibrated with blood glucose information uploaded directly from the OneTouch Ultra Blood Glucose Meter.

The STS Receiver acts as the primary system interface with the user. It contains an LCD screen and 4 buttons for operation. The Receiver displays the date and time information, and Sensor glucose values are updated automatically every 5 minutes. The Receiver displays the Sensor glucose values in mg/dL or mmol/L along with a 1-hour, 3-hour and 9-hour glucose trend graph to provide historical glucose information. Date and time information can be displayed in 12-hour or 24-hour format. In typical use the Receiver will last 5 days before re-charging of the battery is required.

The Receiver has High and Low Glucose Alerts that can be set by the users (as directed by their health care team) to notify users of when the current glucose level is outside of their target glucose range. The STS Receiver also has an automatic Low Glucose ALARM set at 55 mg/dL to warn users of very low glucose levels. Dashed lines on the Receiver trend graphs indicate the current alert level settings. The Low Alert and Low Alarm will vibrate/sound if the current glucose level is below the Low Alert or Low Alarm and their glucose levels are trending in the down direction. The High Alert performs in the same manner; the value and the trend information cause an Alert to occur.

The Receiver also has internal data checks to ensure the quality of the data provided to the user at all times. If the Receiver detects a problem with the Sensor signal or determines the accuracy of the value is inadequate, the Receiver will not display the reading until the minimum accuracy requirement is restored or the signal problem is resolved.

The Receiver contains memory to store up to 30 days of continuous glucose information and a USB communication port for uploading the Sensor data stored to a PC. The STS Receiver is not water resistant and must be kept dry at all times.

## VI. ALTERNATIVE PRACTICES OR PROCEDURES

Periodic glucose self-monitoring using home blood glucose meters will provide information regarding variations in glucose levels.

## VII. MARKETING HISTORY

The STS-7 System has not been marketed in the United States or any foreign country.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Use of the DexCom STS Sensor may cause erythema at the insertion site or adhesive area, edema, and bleeding at the insertion site.

Inaccurate glucose values or inappropriate alerts and alarms provided by the STS-7 System could result in potentially inappropriate administration of insulin or ingestion of carbohydrates.

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## IX. SUMMARY OF PRE-CLINICAL STUDIES

Modifications since the originally approved device were made to the STS Transmitter printed circuit board to enhance glucose signal processing and the STS Sensor Pod for water resistance. The Introducer needle was reduced to a 26-gauge needle, and the STS Receiver algorithm was modified to enhance calibration, signal-processing methods, and for use of the device for up to 7 days. The Pre-Clinical Testing conducted to ensure that the STS-7 System operated in accordance with its pre-determined acceptance criteria to ensure that design input meets design output requirements are described below.

### A. Electromagnetic Compatibility

The STS Transmitter circuit board has been modified since the originally approved Transmitter to enhance signal processing and packet transmission. Therefore STS-7 System testing was conducted with the STS Receiver to ensure electromagnetic emissions were met in accordance with the following test standards:

- EN55011 (Radiated and Conducted Emissions)
- EN61000-4-3 (Radiated Immunity)
- EN61000-4-8 (Magnetic field Immunity)
- FCC Part 95 (Medical Implant Communication Service)

All Transmitters met the requirements of these standards.

### B. Electrostatic Discharge

The modified STS Transmitter for the STS-7 System was subjected to electrostatic discharge testing in accordance with the requirements of EN61000-4-2. Contact (±2, ±4, ±6 kV) and air (±2, ±4, ±8 kV) discharges were applied to multiple points on the Transmitters. All test samples passed functional testing performed following exposure to these discharges.

### C. Environmental Testing

The following additional system-level testing was done on the STS-7 Sensor/Sensor Pod and Transmitter configuration to establish water resistance of the STS-7 Sensor/Sensor Pod/Transmitter:

1. Temperature Humidity Exposure

Sensor Systems were tested in an environmental chamber at 95+5% to -10% humidity and 37±2°C for 72 hours to evaluate the effects of extreme temperatures and humidity on the modified STS-7 Sensor/STS Pod configuration Transmitter. All systems passed the pre-specified requirements after exposure.

2. IP Quality - Water Resistant

Thirty-four STS-7 Sensor/STS Pod/STS Transmitter configurations were tested according to requirements of EN 60529:1992 IPX5 (must withstand a water jet hose nozzle, 12.5 l/min, 1 min/$m^2$ for at least 3 minutes) and IPX7 (must withstand an immersion tank, water-level on enclosure: 0.15 m above top, 1 m above bottom for 30 minutes). All systems passed the pre-specified requirements after exposure.

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### D. Device Integrity Testing

1. 26-gauge Needle Insertion Force

STS-7 Introducer Needle/Sensor configurations were deployed through a moistened chamois to evaluate the needle insertion force. All samples demonstrated an insertion force less than the predetermined acceptance criteria.

2. 26-gauge Needle Bond Strength

Needle assemblies were tested to evaluate the bond strength between the needle and needle carrier. All samples demonstrated bond strength greater than the predetermined acceptance criteria.

3. Contact Resistance

STS-7 Sensors and STS Transmitters were evaluated to determine the maximum change in contact resistance during a 72 hour period with the modified STS-7 Sensor/Pod configuration. All samples demonstrated a contact resistance less than the predetermined acceptance criteria.

### E. Software Validation

Comprehensive testing was performed on the modified algorithm in the STS Receiver to ensure the performance of each of the manufactured devices has met the software design specification and software requirements specifications established for each item. The verification and validation activities are completed according to the FDA guidance entitled "General Principles of Software Validation: Final Guidance for Industry and FDA Staff" released January 11, 2002.

Verification and Validation of the software implementation is accomplished through software code reviews, unit testing, and system level testing. These evaluations verify that the software implementation satisfies the design implementation as defined in the Software Design Document and validate that the software conforms to user needs and intended uses.

## X. SUMMARY OF CLINICAL STUDIES

### A. Pilot Study of 7-Day Effectiveness and Safety of the DexComTM Short Term Glucose Sensor (Feasibility Study-PTL9600)

The purpose of this study was to evaluate the preliminary safety and effectiveness of the DexCom STS-7 when worn over a seven-day period during home use in subjects with diabetes mellitus requiring insulin. This was a nonrandomized pilot study with twenty (20) patients enrolled at one clinical center in the United States.

The study occurred in three (3) Stages. In Stage 1, 5 patients wore two Sensors for up to 7 days, in which one Sensor was removed after Day 5 to evaluate for any moderate to severe irritation. In Stage 2, 5 additional patients were enrolled and wore 2 Sensors for 7 days. Patients were given the option to remove a Sensor after Day 5 if a sensor was irritating; however, no patients opted to do this. Stage 3 enrolled 10 subjects, each wearing 2 Sensors. At each stage patients returned to the clinic one week after removal of the last STS-7 Sensor to examine the insertion sites and document any irritation and/or adverse device effects.

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Results from these studies indicated good glucose tracking by the sensors and there were no moderate or severe irritation events or Unanticipated Adverse Device Effects reported. Only one adverse device effect of mild bleeding at the insertion site occurred throughout all study periods. Overall, the study results showed that that STS-7 Sensor provided meaningful real-time glucose data to the patients for adjunctive use and that the devices were safe to use for up to 168 hours.

**B. Extended Wear Study of the Short Term Glucose Sensor (PTL9610)**

This was a large, multi-center study to evaluate the safety of use of the STS System for up to 7 days to collect data to further develop the STS System. The device was used at home and worn for three (3), 7-day periods in persons with diabetes mellitus requiring insulin. STS values collected were compared to the One Touch Ultra Blood Glucose Meter. This study was a single-armed study conducted with eighty-six (86) subjects enrolled at five clinical sites in the United States.

Subjects were blinded to the Sensor glucose values for the first insertion period, and then unblinded to the glucose display on the second and third insertion periods. A follow-up phone call occurred 6-10 days post-removal of the last Sensor.

No adverse device effects (ADEs) were reported for any of the 86 subjects. Four (4) non-device related adverse events occurred in four subjects (4.7%). No Unanticipated Adverse Device Effects related to the insertion of, removal, wear of the device, or to the utilization of the real-time glucose values, alerts and trends occurred.

Preliminary effectiveness analysis showed no systematic high or low bias as compared to the OneTouch Ultra meter, with a reported R-value of 0.90, a Mean Absolute Relative Difference (MARD) of 16±15% across the 6,465 matched pairs. In addition, a clinical effectiveness analysis was performed, showing that after 14 days of unblinded use, as compared to the first 7 days of blinded use, subjects were able to significantly decrease their time spent in the hypoglycemic range (-33%), significantly increase their time spent in the Target Glucose Range (+18%) and significantly decrease their time spent in the hyperglycemic range (-40%).

This study information was used to derive additional algorithm modifications and enhancements to increase the clinical utility of the STS-7 device.

**C. Effectiveness and Safety Study of the DexCom STS® 7-day Continuous Glucose Sensor (PTL9640)**

1. Overview

The purpose of this study was to evaluate the safety and effectiveness of the DexCom STS-7 System when worn up to 7 days (168 hours) by persons with diabetes mellitus requiring insulin. The primary efficacy endpoint was STS-7 bias as compared to the Yellow Springs Instrument (YSI). Additionally, precision of the STS-7 was assessed on a subset of patients wearing two STS-7 Systems simultaneously. Safety information was collected and characterized by the incidence of Adverse Device Effects (ADEs), Serious Adverse Device Effects (SADEs), and Unanticipated Adverse Device Effects (UADEs) of subjects who participated in the study.

2. Demographics

This study was a non-randomized, single-armed study, with seventy-two (72) subjects enrolled at five clinical study centers in the United States. Thirty-five (48.6%) subjects enrolled were male and 37 (51.4%) enrolled were female. The average age

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of the population studied was 49±14 years. Fifty-four (54) subjects (75.0%) were persons with type 1 diabetes and 18 subjects (25.0%) were persons with type 2 diabetes, requiring insulin therapy. The mean duration of diabetes was 24 ±14 years. Thirty-eight subjects (52.8%) in the population used Continuous Subcutaneous Insulin Infusion (CSII) for insulin therapy, and the remaining 34 subjects (47.2%) were on Multiple Daily Injection (MDI) therapy. The average baseline Hemoglobin A1c was 7.6±1.5%. The Mean Body Mass Index of the subjects was 27.3±6.36 $kg/m^2$.

3. Study Procedures

Following screening, subjects inserted one or two STS-7 Systems at the clinic. During home use, subjects were asked to use two OneTouch® Ultra® Blood Glucose Meters provided to them. Subjects were asked to use the calibration meter for STS-7 calibration requirements and the comparative meter was used for all other fingersticks required for diabetes management. All subjects participated in one 10-hour in-clinic day on Day 1, 4 or 7 of the study to gain additional accuracy information against a laboratory method (YSI Analyzer) and against the OneTouch Ultra Meter. During the in-clinic day, subjects were asked to have blood draws for evaluation of the YSI blood glucose measurements and blood glucose levels were manipulated per the protocol to ensure that the entire STS-reported glucose range could be evaluated. On Day 7, STS-7 System(s) were removed at the clinic and study staff examined insertion sites for any irritation and documented any ADEs. No occlusive dressings were required for showering or bathing during STS-7 System use.

4. Devices Utilized

One hundred and twelve (112) STS-7 Sensors were applied, 12 (10%) of which were applied as replacements. One hundred and four (104) STS Transmitters were used 4 (4%) were applied as replacement Transmitters. One hundred and four (104) Receivers were used and 4 (4%) were applied as replacement STS Receivers.

5. Adverse Events

No adverse events related to use of the device (continuous glucose values and alerts) were reported during the seven-day trial. Overall 89% of patients reported no symptoms of irritation and 11% reported at least one symptom at any insertion site.

6. Subject Discontinuations

None of the subjects withdrew from the study.

7. Results

Development of the STS-7 System, including the final STS-7 Sensor modifications, Transmitter modifications, and algorithm was completed prior to initiation of the PTL9640 study. Performance statistics were calculated using the OneTouch Ultra meter for calibration during real-time use. No post-processing of the data was done on the dataset for calculation of the STS-7 System glucose results.

The STS-7 System glucose values were compared to the Yellow Springs Instrument (YSI) as well as the OneTouch Ultra Meter. Results are described below. The STS-7 and blood glucose values (YSI or OneTouch Ultra) were compared by pairing the STS-7 value that fell within 2.5 to 7.5 minutes after the comparative blood glucose value was collected.

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Results are based on an average calibration fingerstick frequency of 2-3 times per day where patients' average calibration frequency was 4 calibrations on Day 1 and approximately 2 calibrations per day for days 2 through 7. Patients were issued two OneTouch Ultra meters; one was used for only calibration purposes and the second was used for only comparative purposes.

(a.) Performance Evaluation of the STS-7 vs. YSI

Of the 72 patients enrolled, 69 patients provided evaluable data for the YSI analysis. For the In-Clinic evaluation, Bias was evaluated using the Deming regression method. There were 2322 matched pairs collected over days 1, 4, and 7, and the reported Deming Slope and Intercept were 0.86 and 9.53 mg/dL, respectively.

The mean relative difference (RD) and mean absolute relative difference (ARD) of the STS-7 compared to the YSI across the reportable range (40-400 mg/dL) was –7.52%, and 16.7%, respectively. The median RD and median ARD compared to the YSI across the reportable range was –9.8%, and 13.3%, respectively. Table 1 provides these values by glucose concentration range:

**Table 1. STS-7 Mean/Median RD & Mean/Median ARD as Compared to YSI, Stratified by Glucose Concentration Range**

| Glucose Range (mg/dL) | Number of Paired Readings | Mean RD | Median RD | Mean ARD | Median ARD |
|---|---|---|---|---|---|
| 40-60 | 36 | 9.79% | 2.22% | 22.6% | 17.9% |
| 61-80 | 172 | 2.92% | -2.38% | 23.0% | 17.8% |
| 81-180 | 1,077 | -7.67% | -9.16% | 16.9% | 13.2% |
| 181-300 | 865 | -9.82% | -11.0% | 15.0% | 12.8% |
| 301-350 | 119 | -9.88% | -8.95% | 13.5% | 11.2% |
| 351-400 | 47 | -12.9% | -14.4% | 14.1% | 14.4% |

The agreement of the STS-7 System to YSI blood glucose levels was assessed by calculating the percentage of STS-7 System values that were within 20 mg/dL or 20% and 30 mg/dL or 30% of the YSI readings. For values less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose values was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI value was calculated. The percentages of total values within 20 mg/dL or 20% and within 30 mg/dL or 30% of the YSI value were then calculated. The data were further broken down by glucose concentration range. The total number of data pairs considered in this analysis was 2,318. 71% of the values fell within 20 mg/dL/20% of the YSI values and 89% of the STS-7 values fell within 30 mg/dL/30% of the YSI values. Restricting the criteria to 20 mg/dL for values ≤ 80 mg/dL and 30% for values > 80 mg/dL, 87% of the STS-7 values were within 20 mg/dL/30% of the YSI. Detailed results are provided in Table 2.

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**Table 2. Percentage of STS-7 System Results within 20% and 30% of the YSI Measurements, Stratified by Glucose Concentration Range**

| Glucose Range (mg/dL) | Total % (and #) of Paired Readings | % (and #) of Readings within 20% of the YSI reading | % (and #) of Readings within 30% of the YSI reading |
|---|---|---|---|
| 40-60* | 1.55% (36) | 86.1% (31) | 94.4% (34) |
| 61-80* | 7.33% (170) | 68.2% (116) | 91.2% (155) |
| 81-180 | 46.9% (1087) | 68.9% (749) | 84.8% (922) |
| 181-300 | 36.7% (850) | 73.7% (626) | 90.8% (772) |
| 301-350 | 5.48% (127) | 71.7% (91) | 96.9% (123) |
| 351-400 | 2.07% (48) | 68.8% (33) | 93.8% (45) |
| **Overall** | **100% (2318)** | **71.0% (1646)** | **88.5% (2051)** |

***Values less than 81 mg/dL were evaluated by the absolute difference (within 20 mg/dL and 30 mg/dL) from the YSI for this analysis.**

The Clarke Error Grid (CEG) Analysis indicated that 98% of the STS-7 System readings were within the clinically acceptable Zones A and B, the majority of which (70%) were in the CEG A zone (clinically accurate) when the STS-7 was calibrated with the OneTouch Ultra meter and compared to the YSI analyzer.

The following table (Table 3) shows the percentage and number of points falling within each zone across all glucose values and stratified by glucose concentration range.

**Table 3. Clarke Error Grid Results, Overall and Stratified by Glucose Concentration Range**

| Glucose Range (mg/dL) | Percentage of Total Points (and #) | A Percentage (and #) | B Percentage (and #) | C Percentage (and #) | D Percentage (and #) | E Percentage (and #) |
|---|---|---|---|---|---|---|
| 40-75 | 6.43% (149) | 68.5% (102) | 15.4% (23) | 0% (0) | 15.4% (23) | 0.67% (1) |
| 76-180 | 49.4% (1144) | 68.4% (783) | 30.9% (353) | 0.70% (8) | N/A* | N/A* |
| 181-300 | 36.7% (850) | 73.2% (622) | 24.7% (210) | 0.71% (6) | 1.41% (12) | 0% (0) |
| 301-400 | 7.55% (175) | 70.9% (124) | 29.1% (51) | N/A* | 0% (0) | 0% (0) |
| **Overall** | **100% (2318)** | **70.4% (1631)** | **27.5% (637)** | **0.60% (14)** | **1.51% (35)** | **0.04% (1)** |

***N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.**

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(b.) Low and High Glucose Alerts

The Low Glucose Alert was evaluated for its ability to detect low glucose values as determined by the YSI. As presented in Table 4 below, the STS-7 detects low glucose values at or below 70 mg/dL accurately 64% of the time. If you increase the alert to 90 mg/dL, the detection of true events increases to 85%.

**Table 4. Low Glucose (Hypoglycemia) Alert Evaluation**

| STS-7 Alert Level | True Alert Rate* | False Alert Rate** |
|---|---|---|
| 60 mg/dL | 64 % | 79 % |
| 70 mg/dL | 68 % | 63 % |
| 80 mg/dL | 76 % | 45 % |
| 90 mg/dL | 85 % | 36 % |

*** True Alert Rate is the % of time when the blood glucose level was at or below the alert setting and the alert would have sounded.**

**** False Alert Rate is the % of time when the device would have sounded but the blood glucose level was above the alert setting.**

Estimates of how well the adjustable High Glucose Alert performs are presented in the table below. For example, setting the STS-7 High Glucose Alert to 200 mg/dL, the STS-7 System will alert when glucose levels rise above 200 mg/dL 79% of the time. Additionally, 8% of the time when the alert sounds, the glucose level will actually be below 200 mg/dL (False Alert Rate).

**Table 5. High Glucose (Hyperglycemia) Alert Evaluation**

| Alert Setting | True Alert Rate* | False Alert Rate** |
|---|---|---|
| 140 mg/dL | 84 % | 4 % |
| 180 mg/dL | 76 % | 8 % |
| 200 mg/dL | 79 % | 8 % |
| 220 mg/dL | 70 % | 11 % |
| 240 mg/dL | 60 % | 14 % |
| 300 mg/dL | 53 % | 22 % |

*** True Alert Rate is the % of time when glucose level was at or below the alert setting and the alert would have sounded.**

**** False Alert Rate is the % of time when the device would have alerted but the blood glucose level was above the alert setting.**

(c.) Performance Evaluation of the STS-7 vs. OneTouch Ultra meter

For the OneTouch Ultra meter evaluations, 71 patients provided data for the Home Use meter accuracy evaluation. The agreement of the STS-7 System to the OneTouch Ultra blood glucose levels was assessed for the home use portion of the study by calculating the percentage of STS-7 System values that were within 20 mg/dL or 20% and 30 mg/dL or 30% of the OneTouch Ultra readings. For values less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose values was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the OneTouch Ultra value was calculated. The percentages of total values within 20 mg/dL or 20% and within 30 mg/dL or 30% of the OneTouch Ultra value

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were then calculated. The data were further broken down by glucose concentration range. The total number of data pairs considered in this analysis was 3,484. 75% of the values fell within 20 mg/dL/20% of the OneTouch Ultra values and 90% of the STS-7 values fell within 30 mg/dL/30% of the YSI values. Restricting the criteria to 20 mg/dL for values ≤ 80 mg/dL and 30% for values > 80 mg/dL, 88% of the STS-7 values were within 20 mg/dL/30% of the OneTouch Ultra meter. Detailed results are provided in Table 6.

**Table 6. Percentage of STS-7 System Results within 20% and 30% of the OneTouch Measurements collected during home use, Stratified by Glucose Range**

| Glucose Range (mg/dL) | Total % (and #) of Paired Readings | % (and #) of Readings within 20% of the OneTouch reading | % (and #) of Readings within 30% of the OneTouch reading |
|---|---|---|---|
| 40-60* | 3.13%(109) | 89.9%(98) | 96.3%(105) |
| 61-80* | 7.98%(278) | 75.9%(211) | 91.4%(254) |
| 81-180 | 54.7%(1904) | 72.8%(1386) | 87.5%(1666) |
| 181-300 | 30.1%(1049) | 76.6%(803) | 91.7%(962) |
| 301-350 | 3.10%(108) | 81.5%(88) | 93.5%(101) |
| 351-400 | 1.03%(36) | 72.2%(26) | 86.1%(31) |
| **Overall** | **100%(3484)** | **75.0%(2612)** | **89.5%(3119)** |

***Values less than 81 mg/dL were evaluated by the absolute difference (within 20 mg/dL and 30 mg/dL) from the OneTouch Ultra for this analysis.**

(d.) Calibration Stability

The STS System should be calibrated every 12 hours. To demonstrate performance of the STS System over a 12-hour calibration period, 69 Sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period, at 4-hour intervals. Performance was assessed by comparing the % of STS Sensor readings falling within 20 and 30% of the YSI reading in each 4-hour interval, stratified by glucose range. The results in Table 7 show stable performance across intervals at each glucose range. Performance of calibration periods across days 1, 4, and 7 were evaluated and there were no significant differences noted.

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**Table 7. Percentage of STS Readings Falling Within 20% and 30% of the YSI values with Data Stratified in Four-Hour Increments After Calibration and by Glucose Range**

| Time from Calibration and YSI Glucose Range (mg/dL) | Number of Paired Readings | % (and #) of Readings within 20% of YSI | % (and #) of Readings within 30% of YSI |
|---|---|---|---|
| **40-75* mg/dL** | | | |
| 0-4 hours | 47 | 77% (36) | 94% (44) |
| 4-8 hours | 62 | 73% (45) | 90% (56) |
| 8-12 hours | 36 | 64% (23) | 92% (33) |
| **76-180 mg/dL** | | | |
| 0-4 hours | 520 | 64% (335) | 81% (423) |
| 4-8 hours | 371 | 73% (269) | 89% (329) |
| 8-12 hours | 260 | 72% (186) | 85% (220) |
| **181-350 mg/dL** | | | |
| 0-4 hours | 434 | 78% (339) | 92% (400) |
| 4-8 hours | 333 | 67% (224) | 90% (301) |
| 8-12 hours | 210 | 73% (154) | 92% (194) |
| **351-400 mg/dL** | | | |
| 0-4 hours | 21 | 90% (19) | 95% (20) |
| 4-8 hours | 34 | 68% (23) | 91% (31) |
| 8-12 hours | 18 | 28% (5) | 100% (18) |

***The absolute difference from the YSI meter is measured in mg/dL for readings 40-75 mg/dL.**

(e.) Sensor Stability

The STS Sensor provides glucose information for up to 168 hours (166 hours after initial calibration). Performance of the STS-7 System was evaluated according to length of time from Sensor insertion. From the YSI dataset, the percentage of STS-7 System values within 20% and 30% of the YSI readings were evaluated at Days 1, 4, and 7 from insertion. These results were also evaluated by glucose concentration range. Results in Table 8 demonstrate stable performance over Sensor wear time.

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**Table 8. Number (%) of STS Readings within 20% and 30% of YSI Value, Stratified by Day and Glucose Range**

| Day of Wear and YSI Glucose Range (mg/dL) | Total Number (%) of Readings | # (%) of Readings within 20% of YSI | # (%) of Readings within 30% of YSI |
|---|---|---|---|
| **Day 1** | | | |
| 40-75* | 4.08% (36) | 69.4% (25) | 88.9% (32) |
| 76-180* | 47.2% (416) | 52.4% (218) | 77.4% (322) |
| 181-350 | 45.5% (401) | 74.8% (300) | 92.5% (371) |
| >350 | 3.29% (29) | 69.0% (20) | 100% (29) |
| **All (40-400)** | **100% (882)** | **63.8% (563)** | **85.5% (754)** |
| **Day 4** | | | |
| 40-75* | 3.74% (33) | 81.8% (27) | 90.9% (30) |
| 76-180 | 39.2% (346) | 69.4% (240) | 81.2% 281 |
| 181-350 | 36.9% (325) | 62.2% (202) | 88.9% (289) |
| >350 | 1.81% (16) | 75.0% (12) | 93.8% (15) |
| **All (40-400)** | **100% (720)** | **66.8% (481)** | **85.4% (615)** |
| **Day 7** | | | |
| 40-75* | 8.62% (76) | 68.4% (52) | 93.4% (71) |
| 76-180 | 44.1% (389) | 85.4% (332) | 94.9% (369) |
| 181-350 | 28.5% (251) | 85.7% (215) | 93.6% (235) |
| >350 | 3.17% (28) | 53.6% (15) | 89.3% (25) |
| **All (40-400)** | **100% (744)** | **82.5% (614)** | **94.1% (700)** |

***The absolute difference from the YSI meter is measured in mg/dL for readings 40-75 mg/dL.**

(f.) Sensor Life

STS-7 Sensors may be used for up to 168 hours. 111 STS-7 Sensors were applied and 11 Sensors were replaced. Looking only at the STS-7 Sensors that were not replaced during the course of the study, 97 STS-7 Sensors were evaluated to estimate how many sensors continued to work for up to168 hours. Of those 97 STS-7 Sensors there were no insertion problems. The results showed that 75% of the sensors lasted between 145-168 hours with 81% lasting more than 144 hours. Of the 24 STS-7 Sensors that did not last beyond 144 hours, 14 became non-functional because of device failure (Early Sensor Shutoff), 7 fell off the insertion site during use, 2 ended early because the STS Pod came unglued from the adhesive, and 1 stopped functioning because of an STS Transmitter Connection Issue.

Of these STS-7 Systems evaluated, 69% provided more than 1,537 readings (approximately 219 readings per day).

## XI. CONCLUSIONS DRAWN FROM STUDIES

The results of the pre-clinical verification/validation testing and clinical trials to assess the performance of the STS-7 Continuous Glucose Monitoring System with real-time glucose readings and trend information establish reasonable assurance that this system is safe and effective for its intended use when utilized in accordance with product labeling.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

## XII. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Clinical Chemistry and Toxicology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## XIII. CDRH DECISION

FDA issued an approval order on May 31, 2007.

This PMA Supplement was granted expedited review status on June 19, 2006 because the availability of the device as a tool in diabetes management is in the interest of public health.

## XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See Approval Order.