

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Continuous glucose monitor (CGM) enabled insulin infusion pump

Device Trade Name: Animas Vibe System

Device Procode: MDS, OYC

Applicant's Name and Address: Animas Corporation
200 Lawrence Drive
West Chester, PA 19380

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P130007/S004

Date of FDA Notice of Approval: December 24, 2015

Priority Review: Not applicable

The original PMA P130007 was approved on November 25, 2014 and is indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes, and is intended to complement, not replace, information obtained from standard home glucose monitoring devices.

The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication to add use in pediatric patients (age 2 and older – the device was previously approved for patients 18 and older) and to add an alternate sensor insertion site on the upper buttocks for the pediatric population.

II. INDICATIONS FOR USE

The Animas Vibe System consists of the Animas Vibe Insulin Pump paired with the Dexcom G4 Platinum CGM sensor and transmitter.

The Animas Vibe Insulin Pump is intended for the continuous subcutaneous infusion of insulin for the management of insulin-requiring diabetes. It can be used solely for continuous insulin delivery or as part of the Animas Vibe System to receive and display continuous glucose measurements from the Dexcom G4 PLATINUM Sensor and Transmitter.

The Animas Vibe System's continuous glucose monitoring (CGM) is indicated for detecting trends and tracking patterns in persons (age 2 and older) with diabetes, and is intended to complement, not replace, information obtained from standard home glucose monitoring devices. CGM 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 results from the Dexcom G4 PLATINUM Sensor and Transmitter should be based on the trends and patterns seen with several sequential readings over time.

The Animas® Vibe™ System is intended for single patient use in persons age 2 and older and requires a prescription.

III. **CONTRAINDICATIONS**

The following are listed in the labeling:

Contraindications for using the Animas® Vibe™ Insulin Pump

Insulin pump therapy is not recommended for people with diabetes who are unwilling or unable to:

- Test their blood glucose (BG) levels four to six times per day or as recommended by their Healthcare Professional (HCP).
- See their HCP regularly.
- Respond to pump alerts, warnings, and alarms because they are visually or hearing impaired.

Not following these guidelines will make it hard for you to determine how much insulin you need based on your current health status and the foods you eat. Not seeing your HCP on a regular basis will not allow them to make adjustments to your pump settings and diabetes treatment plan that would be beneficial to your health. Not being able to respond to pump notifications means you may not be aware of certain health conditions or problems with your pump that require your attention.

Contraindications for using the Dexcom G4 PLATINUM Sensor and Transmitter

- The Dexcom G4 PLATINUM Sensor and Transmitter must be removed prior to Magnetic Resonance Imaging (MRI), computerized tomography (CT) scan, or diathermy treatment. The Dexcom G4 PLATINUM Sensor and Transmitter have not been tested during MRI or CT scans or with diathermy treatment, and it is unknown if there are safety or performance issues.
- Taking acetaminophen-containing medications while wearing the Sensor may falsely raise your Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body.

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the Animas Vibe System labeling.

V. **DEVICE DESCRIPTION**

The Animas Vibe System (“Vibe System”) consists of the Animas Vibe Insulin Pump (“The Pump”) and Dexcom G4 Platinum CGM System. The Vibe System includes an insulin infusion pump, designed to communicate via Radio Frequency (RF) telemetry with the Dexcom CGM transmitter (“the Transmitter”) to display CGM information in addition to infusion pump data. The insulin infusion pump delivers insulin through an infusion set for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes. The Dexcom G4 CGM System (“the Sensor”) provides continuous measurements of glucose in the tissue over the range of 40 to 400 mg/dL for up to seven days of use and displays glucose values and trends for patients with diabetes mellitus on the pump. The Vibe System provides glucose trends, alerts and a low glucose alarm.

Description of System Components

The Animas Vibe System is comprised of the following components:

Dexcom G4 PLATINUM Sensor

The Dexcom G4 Platinum Sensor is comprised of a sensor applicator, an adhesive pad and transmitter mount and the sensor probe. The G4 Sensor is a sterile device inserted by the user into the abdominal subcutaneous tissue using the applicator. The applicator is adhered to the surface of the skin with a standard medical grade adhesive pad. The applicator contains a 26-gauge introducer needle that contains the sensor probe. The needle is not exposed, or even visible, to the user during the insertion process. After deployment of the introducer needle, the needle is retracted back into the applicator. The applicator is then detached and disposed by the user, exposing a transmitter mount ready for placement of the transmitter.

The sensor probe remains beneath the surface of the skin and uses the enzyme glucose oxidase to convert the glucose in the interstitial fluid around the sensor into an electrical current proportional to the ambient glucose concentration. The sensor continuously measures glucose in the interstitial fluid every five minutes. The flexible sensor has an adhesive to adhere the sensor to the skin. The sensor that is adhered to the skin is replaced every seven days.

Dexcom G4 Platinum Transmitter

The Dexcom G4 CGM Transmitter is a miniature radio transmitter operating at an internationally-accepted radio frequency. After sensor insertion and removal of the applicator, the user manually places the G4 CGM Transmitter into the transmitter mount on the adhesive pad already attached to the skin. The Transmitter contains all the electrical circuitry necessary for the operation of the electrochemical sensor and also all the radio frequency circuitry necessary to transmit the sensor signal to the receiver in the pump. The transmitter collects the electrical current from the sensor and transmits the sensor signal wirelessly to the Animas Vibe Insulin Pump at 5 minute intervals. The Transmitter is programmed with a unique identification serial number that is manually entered into the

corresponding pump by the user in order to establish a secure wireless communication link between the two hardware components. The Transmitter is reusable and contains non-replaceable batteries which allow the device to be used by a single user for the lifetime of the encased batteries, which is typically 6 months from initial use. The transmission distance is at least 12 feet.

Animas Vibe Insulin Pump

The Animas Vibe Insulin Pump delivers insulin through an infusion set for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes.

The Animas® Vibe™ Insulin Pump is an external cartridge (syringe) pump and delivery system for ambulatory use by patients with insulin requiring diabetes who would benefit from a continuous insulin infusion process. The pump delivers a prescribed dosage of insulin as a single programmable bolus or at multiple programmable basal rates.

In addition to CGM data, the Animas® Vibe™ Insulin Pump will also display established Animas platform insulin-delivery information: set up information, dosage history, alarms, error and warning messages, device status and self-test capabilities. The Animas® Vibe™ Insulin Pump will not use the continuous glucose monitoring (CGM) data to calculate insulin doses. The CGM data is being provided on the pump screen only as a convenience to the user.

The Animas® Vibe™ Insulin Pump consists of the following subsystems:

- A disposable insulin cartridge for storage of insulin.
- Battery compartment for holding a battery (the pumps energy source).
- Electronics, drive mechanism, software and display which form the core of the pump.

The insulin cartridge is a proprietary syringe comprised of a barrel and a plunger. The cartridge is filled with insulin by the user and is placed in a dedicated housing inside the pump. Within this housing, the cartridge plunger interfaces with a piston, a component of the pump drive mechanism. During the pump delivery sequence, a brushless dc motor drives a speed-reducing gear train and precision lead screw. The lead screw's rotational motion is translated to a linear motion by the (non-rotating) piston. The forward motion by the piston applies a force to the cartridge plunger, which results in the delivery of insulin into the infusion set to the patient via the cannula. The volume of insulin delivered is directly dependent on the displacement of the plunger.

The Animas® Vibe™ Insulin Pump is a prescription device intended for home use and has been designed to withstand the environment typically seen by the patient in the home environment. The Animas® Vibe™ Insulin Pump includes a light emitting diode color display with an adjustable brightness. The design provides protection against fluid ingress (rated IPX8) and has also been designed to conform to relevant electromagnetic compatibility, drop-testing and electrostatic discharge (ESD) standards for performance in the home environment.

The pump software provides the intelligence for key operational functions such as user interface, error monitoring, status reporting and history recording. A glucose and RF engine are also included in the pump electronics to capture process and display CGM sensor signals and information.

The Vibe Pump has internally programmed algorithms to receive the wireless sensor signal from the Transmitter and convert the Sensor measured signal to a reading in mg/dL. The Vibe Pump contains embedded software that drives the Pump user interface and signal processing required for glucose reading calculations, trend information displays, alerts and alarms, and signal processing algorithms. The Vibe Pump also contains calibration and signal processing algorithms required to convert the Sensor’s electrical signal to glucose values in mg/dL that can be displayed to the user.

Calibrations are performed twice daily by the patient using standard commercially-available blood glucose meter devices and entered manually by the patient into the Animas Vibe insulin pump through a data entry menu. After calibrating the system, the Pump automatically displays the current glucose value, trend graphs of recent glucose values and rate of change arrows once every five minutes. The Animas Vibe Insulin Pump also contains circuitry to provide audible or vibratory alerts for high and low glucose values.

The configurable pump High and Low Glucose Alerts can be set by the user in consultation with their health care team to provide warnings when their current glucose level is outside of their target range. Dashed lines on the receiver screen indicate the current alert level settings. The user can configure the Pump to provide audible, vibratory or combined audible and vibratory alerts. The pump also contains a non-configurable low glucose alarm at 55 mg/dL to provide users additional warning of hypoglycemia.

The Vibe System has proprietary algorithms to check for the integrity of the continuous glucose monitoring signal. If the System detects a problem with the Sensor signal or determines that the calibration is beyond an expected value, then the pump will not display a glucose value until the signal quality or calibration has been restored to an acceptable level.

Model (Catalog) numbers

The following is a list of catalog numbers of the full product line for the Animas Vibe pump the model.

Vibe Adult SKUs (Age 18 and above)	
115-51X-XX Revenue Kit, Vibe Adult	
11551000	Rev Kit, Vibe Adult Blu,mg,US
11551100	Rev Kit, Vibe Adult Blk,mg,US
11551200	Rev Kit, Vibe Adult Sil,mg,US
11551400	Rev Kit, Vibe Adult PGL,mg,US
11551500	Rev Kit, Vibe Adult LGN,mg,US

115-20X-XX Replacement Kit, Vibe Adult	
11520000	Rep Kit, Vibe Adult Blu,mg,US
11520100	Rep Kit, Vibe Adult Blk,mg,US
11520200	Rep Kit, Vibe Adult Sil,mg,US
11520400	Rep Kit, Vibe Adult PGL,mg,US
11520500	Rep Kit, Vibe Adult LGN,mg,US

Vibe Peds Older SKUs (Age 8-17)	
116-51X-XX Revenue Kit, Vibe Peds (P2 Older)	
11651000	Rev Kit, Vibe Peds P2 Blu,mg,US
11651100	Rev Kit, Vibe Peds P2 Blk,mg,US
11651200	Rev Kit, Vibe Peds P2 Sil,mg,US
11651400	Rev Kit, Vibe Peds P2 PGL,mg,US
11651500	Rev Kit, Vibe Peds P2 LGN,mg,US
116-20X-XX Replacement Kit, Vibe Peds (P2 Older)	
11620000	Rep Kit, Vibe Peds P2 Blu,mg,US
11620100	Rep Kit, Vibe Peds P2 Blk,mg,US
11620200	Rep Kit, Vibe Peds P2 Sil,mg,US
11620400	Rep Kit, Vibe Peds P2 PGL,mg,US
11620500	Rep Kit, Vibe Peds P2 LGN,mg,US

Vibe Peds Younger SKUs (Age 2-7)	
118-51X-XX Revenue Kit, Vibe Peds (P1 Younger)	
11851000	Rev Kit, Vibe Peds P1 Blu,mg,US
11851100	Rev Kit, Vibe Peds P1 Blk,mg,US
11851200	Rev Kit, Vibe Peds P1 Sil,mg,US
11851400	Rev Kit, Vibe Peds P1 PGL,mg,US
11851500	Rev Kit, Vibe Peds P1 LGN,mg,US
118-20X-XX Replacement Kit, Vibe Peds (P1 Younger)	
11820000	Rep Kit, Vibe Peds P1 Blu,mg,US
11820100	Rep Kit, Vibe Peds P1 Blk,mg,US
11820200	Rep Kit, Vibe Peds P1 Sil,mg,US
11820400	Rep Kit, Vibe Peds P1 PGL,mg,US
11820500	Rep Kit, Vibe Peds P1 LGN,mg,US

Dexcom CGM	
10030001	Dexcom G4 PLTNM Sensor 1pk US
10031001	Dexcom G4 PLTNM Sensor 4pk US
10034001	Dexcom G4 PLTNM Transmitter US

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the control of diabetes. Control of diabetes can be achieved through a combination of methods and behaviors. Self-behaviors include healthy eating, taking medications, as appropriate, and being active. Persons with diabetes may also administer insulin by injection or by using other insulin infusion pumps as prescribed by his/her physician. Methods of controlling glucose levels (glycemic control) have been shown to reduce severe diabetes-related complications. Methods of monitoring glycemic control include periodic measurement of Hemoglobin A1c (HbA1c), which reflects average blood glucose levels over a three month period. Self-monitoring of blood glucose using glucose meters and test strips provides quantitative measurements of fingerstick blood glucose at a single point in time for patients and their healthcare providers to monitor the effectiveness of glycemic control and make more immediate treatment modifications.

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Animas® Vibe™ System as detailed in this submission has not been marketed in the United States for the pediatric indications. However, the Animas Vibe System with pediatric indications has been commercially available outside the United States in the following regions; European Union, Asia Pacific and Canada

The Animas Vibe system is comprised of previously approved components: the Sensor and Transmitter of the FDA PMA-approved Dexcom G4 Platinum Continuous Glucose Monitoring System (P120005) combined with the FDA PMA-approved Animas Vibe System for use in patients older than 18 years old (P130007). Those devices have been marketed since their respective approvals.

The device has not been withdrawn from marketing for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

Potential device-related non-serious events related to CGM or insulin pump use include:

- Skin irritation or redness
- Infection
- Pain or discomfort
- Bruising

- Edema
- Rash
- Bleeding
- Allergic reaction to adhesives
- Hypoglycemia from over-delivery of insulin
- Hyperglycemia and ketosis possibly leading to ketoacidosis due to pump malfunction, or problems with the cannula, needle, or insulin infusion set tubing resulting in cessation of insulin delivery
- Loss of communication between the pump and the sensor resulting in CGM values, alarms, and alerts not being available to the user
- Catheter occlusion resulting in missed insulin dosing
- Catheter dislodgement or fracture during infusion set insertion resulting in injury and/or inability to administer insulin
- Failures of the infusion set or at infusion site resulting in inability to administer insulin
- Mechanical or battery failures resulting in interruptions in insulin delivery or incorrect insulin delivery

Sensor breakage with fragments retained under the skin and catheter fracture during infusion set insertion are potential procedure-related complication. Based on post-market experience with similar devices and the results observed in this clinical study, the occurrence and severity of these events do not raise major concerns.

One potential risk of combining the CGM and the pump is that the user might be more inclined to use the CGM data in an unapproved way to determine their insulin dose. Inaccurate sensor results, if used to make dosing decisions, may lead to hypo- or hyperglycemia. However, no further complications are expected due to the pump being combined with the CGM as a system beyond the potential complications of the pump or CGM alone.

Like other insulin pumps, there is an inherent risk that patients who do not use the system as instructed (nonadherence) could harm themselves. Patients should be informed that sensor interstitial glucose values should not be used to make insulin dose decisions and that all threshold alerts and alarms should be confirmed with a blood glucose measurement. Other risks include the possible dangers of over delivery and under delivery of insulin. Over delivery of insulin can result in very low blood glucose levels and under delivery of insulin can result in very high blood glucose levels. This could be the result of problems with the pump or problems with the infusion set. It may also be the result of the user not making the right decisions for how much insulin to take.

The risks of actions taken based on false positive hyperglycemic readings include inappropriate or excessive administration of insulin and failure to treat hypoglycemia. These inappropriate treatments could result in or prolong hypoglycemia and result in

seizures, loss of consciousness, or death. The risks of actions taken based on false positive hypoglycemic readings include failure to administer insulin and failure to treat hyperglycemia. False positive high alerts and low alerts and alarms may increase the number of unplanned blood glucose checks; and disrupt patient activity and sleep. If the false positive rate is too high it can result in ‘alarm fatigue’ and patients may deactivate these alerts/alarms.

The risks of actions taken based on false negative hyperglycemic readings include failure to administer or insufficient administration of insulin and inappropriate administration of extra carbohydrate. These inappropriate treatments could prolong or induce hyperglycemia. The risks of actions taken based on false negative hypoglycemic readings include inappropriate administration of insulin or failure to administer or insufficient administration of extra carbohydrate. These inappropriate treatments could result in or prolong hypoglycemia and result in seizures, loss of consciousness, or death. Failure to give accurate high and low alerts and alarms will prevent the patient from having the opportunity to perform unplanned blood glucose tests and treat as instructed by their healthcare providers.

The CGM component is to be used for tracking and trending glucose levels. The risk related to either an inaccurate sensor value outside of the patient’s normal range or a false alert or alarm is the risk of performing an unnecessary additional blood glucose test to confirm the erroneous sensor reading. The risk of medical harm may be mitigated through labeling which emphasizes that patients should confirm all CGM readings prior to making treatment decisions. The risks of the device failing to alert an asymptomatic user to a high or low blood sugar is no greater than that associated with traditional blood glucose monitoring.

IX. SUMMARY OF PRECLINICAL STUDIES

The Dexcom G4 Platinum CGM component was approved for pediatric patients aged 2-17 years in the upper buttocks and abdomen under P120005/S002. As such, no new preclinical or clinical studies were conducted using the CGM device as part of the Animas Vibe Pump System. See the SSED for P120005/S002 for information about performance of the Dexcom Gen 4 Platinum CGM in pediatric patients and the original P130007 for the performance of the Animas Vibe System. (Note: the software included in the Dexcom G4 Platinum CGM component for this supplement [P130007/S004] is different from the software approved in P120005/S031 which improved the accuracy in the pediatric population).

A. Laboratory Studies

The nonclinical studies focused on software verification testing required based on the addition of the pediatric warning and ongoing anomaly resolution. The labeling and the receiver display the following warnings regarding use of this system in the pediatric population:

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

The entire Animas Vibe Software test suite was re-executed. All tests were performed on production level devices.

Protocols, test reports and acceptance criteria have been reviewed and found to be acceptable.

The following functionality of the Animas Vibe Pump and System was tested:

- Case integrity testing
- Dual vent functionality
- Display functional testing
- Keypad button functional testing
- Vibrator motor functional testing
- Audio piezo functional testing
- Real time clock functional testing
- Infrared interface functional testing
- RF CGM interface functional testing
- Pump rewind
- Load cartridge
- Prime and fill cannula functional testing
- Occlusion detection functional testing
- Loss of prime functional testing
- Low insulin functional testing
- Delivery functional testing

Design Verification Activities

Product and component verification testing was completed to demonstrate that the finished device performs in accordance with design specifications and is further described in the table below.

Pump and System Qualification

Insulin pumps were subjected to environmental and functional testing to ensure they continue to function normally even when exposed to extreme environmental conditions. Qualification testing of the pump and accessories, including cartridge, consisted of environmental stress conditioning including drop testing, pump cleaning, electrostatic discharge, mechanical vibration, storage temperature, humidity and atmospheric pressure and mechanical rigidity and strength. Environmental exposure testing confirms the pump remains functional after temperature, vibration and shock exposures are applied to the pump. Basal and Bolus delivery performance met the accuracy specifications at the minimum, intermediate, and maximum settings.

System level testing was conducted to verify that the system components worked together, and communication was maintained between components per specifications.

Pump and system level testing occurred over a range of environmental and test conditions. In many cases, devices were pre-stressed before undergoing additional functional testing.

Test	Purpose	Acceptance Criteria	Results
Pump Dimension, Weight, External Materials, Colors and Enclosure Finish	Verify pump design requirements.	Pump Dimension, Weight, External Materials, Colors and Enclosure Finish meet design requirements.	Pass
Real Time Clock (RTC)	Verify accuracy and non-volatility of pump's RTC.	RTC accuracy +/- 5 min over 28 days. RTC accuracy +/- 3 min over 12 hours after battery charge.	Pass
Pump RF Interface Testing	Verify pump firmware implements RF requirements.	Receive transmitter signal in range 2.4000-2.4835GHz. Min. 3 week battery life with Energizer L91 lithium battery.	Pass
RF Sensitivity	Verify pump receiver receives signals	Pump RF receiver receives signals at power level -70dBm or higher.	Pass
Operational Temperature, Humidity, Altitude	Verify pump meets functional requirements across operational specifications.	Functional tests at operational conditions: 5°C and 20% RH 5°C and 90% RH 40°C and 20% RH 40°C and 90% RH 700 hPa 1060 hPa	Pass
Mechanical Vibration	Verify pump meets mechanical vibration stress requirements.	IEC 60601-1-11, Broadband random vibration test.	Pass

Drop Testing	Verify pump meets functional requirements after drop test.	Pump is operational with no visible degradation to display after 1 meter drop.	Pass
ESD Compliance	Pump complies with immunity test levels for contact and air discharge.	IEC 60601-2-24 criteria for ESD used.	Pass
RFI Testing EMI/EMC Compliance	Pump complies with RFI, magnetic field requirements.	IEC 60601-2-24 criteria for RFI, magnetic field used.	Pass
Dielectric Withstand Compliance	Pump meets dielectric withstand compliance requirements.	IEC 60601-2-24 criteria for safety requirements after IPX7 and IPX8 testing.	Pass
Leakage Current Compliance	Verify pump is compliant with leakage current requirements.	IEC 60601-2-24 criteria for Leakage current test under type BF category and after pre-stress and IPX8 and IPX7 testing.	Pass
Over-Delivery Single Point Failure	Verify over-delivery under a single-point failure meets requirement.	An over-delivery under a single-point failure < 2U.	Pass

Audio Alert Volume Testing	Verify audio alert volume.	IEC 60601-2-24 criteria for volume of auditory alarm signals.	Pass
Vibrator Motor Testing	Verify operation of pump vibration motor.	Minimum vibration 0.2 g.	Pass
Pressure Equalization and Vent Occlusion	Verify pump meets design requirements for pressure and vent occlusion.	Equilibrate pressure from 4.7 psig to 1.3 psig in ≤ 300 seconds.	Pass
Battery Type Requirement	Verify recommended battery type is specified in Owner's Booklet.	Energizer L91 Lithium battery recommended in Owner's Booklet.	Pass
Battery Shorting Testing	Verify pump external temperature does not exceed standard.	IEC 60601-1, clause 11	Pass
Basal Rate Accuracy	Verify pump meets basal rate accuracy requirements.	Basal rate accuracy +/- 5% across range of basal rates (0.025 U/Hr – 25 U/Hr) after pre-stress testing.	Pass

Normal/Audio Bolus Delivery Rate Timing	Verify bolus delivery time.	250 msec – 1 sec for 1 U normal and audio bolus.	Pass
Extended Bolus Delivery Rate Timing	Verify extended bolus delivery time.	180 sec \pm 2 sec	Pass
Small Basal Volume Delivery	Verify small basal volume delivery	Volumes < minimum volume (0.0092 U) accumulate until min volume is reached.	Pass
Bolus Dose Accuracy	Verify pump meets bolus dose accuracy requirements.	+/- 5%	Pass
Rewind Maneuver	Verify pump rewind meets requirements.	Complete rewind in <130 sec. Fully rewound to ½ filled cartridge position in < 55 sec.	Pass
Cartridge and Loss of Prime Detection	Verify pump load and prime meet requirements.	Detect absence of Cartridge Terminate load cartridge when force > 0.6 lbf	Pass

Prime Maneuver – Delivery Time Testing	Verify pump delivery time meet requirements.	Prime 10 U in 3-6 sec.	Pass
Prime Maneuver – Max Volume	Verify pump prime meet requirements.	Prime volume 20 ± 2 U or until button released.	Pass
Occlusion Threshold	Verify pump occlusion is detected.	Occlusion threshold ≤ 35 psi	Pass
Empty Cartridge	Verify pump detects empty cartridge condition.	Alarm occurs prior to cartridge empty.	Pass
Cleaning	Verify pump functionality and no deterioration to external surface.	Visual inspection and functionality testing.	Pass
IPX8 Testing	Verify pump functionality and no water ingress or degradation due to water testing.	IEC 60529 on pre- stressed pumps.	Pass

Mechanical Rigidity and Strength	Verify pump functionality, CGM communication, and display work properly.	IEC 60601-1 Push Test	Pass
FCC	Verify pump adheres to FCC limits.	FCC CFR Title 47, part 15	Pass
OLED screen	Verify resolution of OLED screen	Per internal requirements.	Pass
Keypad Design	Verify pump keypad design meets requirements.	Requirements for material, graphics, and pushbutton type.	Pass
Pump Vent Testing	Verify pump vent requirements.	Vent from 8.50 to 0 psig in <= 30 sec.	Pass
Battery Housing Mechanical Construction	Verify battery reversal will not damage pump.	IEC 60601-2-24	Pass

Occlusion Sensitivity – Basal, Bolus	Verify occlusion detection time during basal and bolus delivery.	Occlusion detection time based on delivery rate.	Pass
RF Communication Testing	Verify firmware implements communication requirements.	Communication between pump and CGM is synced and functions as intended.	Pass
CGM Data Reception	Verify communication with single, recognized CGM transmitter.	Communication with pump is activated and maintained as intended without interference from other devices.	Pass
Bolus Delivery Timing – Not to Exceed	Verify timing of pump bolus delivery.	Bolus delivery time depends on delivery speed and bolus size.	Pass
Shipping and Handling Compliance	Verify compliance of storage, shipping, and handling conditions.	ISTA 2A	Pass
RF Frequency Measurements at Temperature	Verify RF packet reception with extreme frequency variability.	Pump receives RF packets from CGM within system operating temperature range of 10°C-40°C.	Pass

Storage Temperature, Humidity, and Altitude	Verify compliance with storage, shipping, and handling conditions.	Temp: -20°C – 60°C RH: 10%-100% Atm. Pressure: 500 hPa – 1060 hPa	Pass
Positive and Negative Height Differential	Verify fluid displacement when pump is located at positive and negative height differentials from infusion site.	Volume displacement not to exceed 0.01 mL in 2 hours when pump is 18 inches above infusion site. Volume displacement not to exceed -0.01 mL in 2 hours when pump is 18 inches above infusion site.	Pass
Altitude Shock	Characterize pump performance at extreme atmospheric pressure conditions.	Characterization study.	Pass
ESD Stress Test	Verify functional performance after being subjected to high voltage levels of ESD.	No permanent degradation, loss of function or data loss.	Pass
Moulding Stress Relief Compliance	Pump complies with moulding stress relief requirement	IEC 60601-1	Pass
Impact Compliance	Pump complies with impact requirement.	IEC 60601-1	Pass

Loss of Prime Detection	Verify pump detects absence of cartridge and activates warning.	Detection of absence of cartridge and warning activated.	Pass
CGM Transmission Interference	Verify system recovers from EMI.	Communication re-established or error displayed within 45 minutes.	Pass
CGM Multiple User	Verify exclusivity of data communication.	Communication is exclusive between pump and recognized CGM. No data transmission from other CGMs.	Pass
CGM Range Test	Verify RF communication between CGM and pump.	RF communication when CGM and pump are within 12 feet, line of sight.	Pass
Battery Life Testing	Verify system meets requirements for battery life and battery alarms.	Minimum battery life: 3 weeks with recommended battery under normal use. Replace battery alarm at least 3 minutes prior to battery depletion.	Pass
History Data	Verify non-volatility of pump history data and CGM history data.	Pump history data and CGM history data will not be lost due to loss of power caused by removal of battery.	Pass

Software Verification and Validation

Comprehensive verification and validation testing was conducted to confirm that the software used in the Animas Vibe Pump System meets all specified requirements and that the software will operate reliability and safely under normal or abnormal use conditions.

The software verification and validation were carried out in accordance with the FDA's "General Principles of Software Validation: Final Guidance for Industry and FDA Staff." Software development activities included establishing detailed software requirements, linking requirements with associated verification tests, software code reviews, unit testing, system level testing and defect tracking and dispositioning to ensure the software conforms to patient needs and intended uses.

Package and Shipping Testing

Packaging shipping and handling testing were re-executed as a minor package design change to the pump revenue kit was performed. The outer dimension of the tertiary (outer) shipping container is smaller for the pediatric configuration. Animas Vibe Insulin Pump Kits were packaged using standard materials and methods and subjected to shipping tests per the ISTA Procedure 2A guidelines. All pumps passed the inspection and functional testing after the shipping and handling tests.

Human Factors Testing:

This supplement uses human factors studies to evaluate the performance of this system, specifically the pump, in pediatric patients (2-17 years) to support the expanded indication. Non-clinical studies for this system were limited to validation activities for the minor software modifications required to include warnings specific to pediatric patients (listed in section IX.A.). These evaluations were focused on the pump, the CGM system and labeling comprehension. Usability evaluations were performed that included critical device tasks (listed below as pump tasks and CGM tasks) and results of the study demonstrated the potential benefits of the device outweighed the risks.

Usability Testing:

The summative testing included a total of forty-five (45) pediatric patients that were considered to be active managers (ages 8-17) took part in the pump and CGM studies. That is, older children would likely begin to use the pump to make decisions on insulin dosing and/or enter the doses as instructed by their parent/caregiver. Children aged 2-7 would not typically manage pump use themselves, and their parents/caregivers would typically control their insulin dosing, so these ages were not assessed in this human factors analysis. Thirty-six (36) participants performed the pump tasks; and 17 participants performed the CGM tasks. Eight (8) participants completed both the pump and CGM tasks. Tasks that were considered "advanced features" (i.e., Set temporary basal rate and combination bolus) were only assessed in those participants that stated they use these feature (13 and 9 subjects, respectively). The participants received one-on-one training on the device at least 24 hours prior to the testing and then took part in the usability test session. At least one parent

accompanied the participants to both the training and test sessions. The study was conducted over a period of seven weeks between October and December 2014 at four research facility locations. The pumps did not contain any insulin and no needles were used during the study; it was a simulated use study.

The results of each task were assessed using the observational data gathered from the study. The results were based on six outcome score measures. All of the participants fell into one of the 3 following categories: Unassisted (successful completion without any observed use errors, usability issues, close calls, or assistance from moderator), Recovered (participant experienced some usability issues, but was able to recover and complete task without assistance from moderator), Error (Participant was unable to complete task successfully, either because he/she did not know what to do or was unaware that he/she did not complete the task successfully).

Subjects were assessed on the following tasks for pumps and CGMs:

Pump Tasks:

- Change Battery
- Prime after battery change
- Bolus (ezCarb)
- Bolus (ezBG)
- Reload cartridge
- Prime after cartridge change
- Suspend pump
- Resume pump
- Review bolus history
- Adjust I:C ratio
- Adjust basal rate
- Adjust contrast
- Set temp basal
- Combination bolus

With the exception of Change battery (75%), Prime after battery change (78%) and Adjust basal rate (68%), at least 80% of the participants successfully completed all the tasks unassisted.

CGM Tasks:

- Set transmitter ID
- Set high/low alerts
- Simulate sensor insertion
- Start new CGM session
- Simulate wait 2 hours
- Calibrate CGM sensor
- Review CGM data

- Suspend pump
- End CGM session
- Respond to CGM errors, alerts, and warnings.

For CGM tasks, participants were able to successfully complete tasks 88-100% of the time unassisted.

The results of the human factor studies demonstrated that the intended users of the system are able to perform the required tasks of the system.

Labeling Comprehension Study:

Thirty (30) pediatric participants' ages 11 to 17 who were considered to be active self-monitors took part in the labeling comprehension study. No training was given prior to completing the study and at least one parent accompanied the participants to the test session. The results of the comprehension study demonstrate that the users were able to successfully read and comprehend the information in the owners' booklet.

B. Animal Studies

No animal studies were conducted using the Animas Vibe System.

C. Additional Studies

None

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

Dexcom performed a clinical study to establish a reasonable assurance of safety and effectiveness with the Dexcom G4 Platinum CGM System for detecting trends and tracking patterns when used as an adjunct to blood glucose testing in subjects with diabetes mellitus. Please see P120005/S002 SSED for details on this clinical study, including Financial Disclosure information.

No additional clinical study was conducted using the Animas Vibe System.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Clinical Chemistry and Clinical 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.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The results of the pivotal clinical study performed in P120005/S002 establish a reasonable assurance of safety and effectiveness with the Dexcom G4 Platinum CGM System for detecting trends and tracking patterns when used as intended, adjunctively with blood glucose testing in subjects with diabetes mellitus. See the P120005/S002 SSED for additional information.

No additional clinical study was required for the Animas Vibe System. The preclinical data presented above (Section IX) establishes a reasonable assurance of safety and effectiveness for the Animas Vibe System.

The results of the pre-clinical testing demonstrate that the Animas Vibe System complies with the applicable voluntary standards for biocompatibility, sterilization, Electromagnetic Compatibility and Safety. The device passed all the testing in accordance with national and international standards. Internal verification and validation testing confirmed that product specifications were met which support the intended use and technological characteristics. The verification and validation of the device software were completed according to the FDA guidance entitled General Principles of Software Validation: Final Guidance for Industry and FDA Staff released January 11, 2002.

The summative human factors study examined the usability of the Animas Vibe System in pediatric patients. The results of the usability study and the labeling comprehension study demonstrate that the representative users can successfully complete the specified tasks using the system without producing patterns of failures or use errors.

The clinical testing performed in P120005/S002 for the Dexcom G4 Platinum CGM System for pediatric indications, and the non-clinical and human factors/usability summative testing completed on the Animas Vibe System and its components for this PMA, demonstrate that the Animas Vibe System is sufficiently effective in the intended use population and support the operation of this device as a system.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory data of the Animas Vibe System (described above) as well as data collected in a clinical study conducted to support PMA approval of the Dexcom G4 Platinum CGM System as described in the SSED for P120005/S002.

Potential device-related non-serious events related to CGM or insulin pump use include:

- Skin irritation or redness
- Infection

- Pain and discomfort
- Bruising
- Edema
- Rash
- Bleeding
- Allergic reaction to adhesives
- Inadvertent or unintended insulin dosing (e.g., from rolling onto the pump while sleeping or tampering by young children)
- Hypoglycemia from over-delivery of insulin
- Hyperglycemia and ketosis possibly leading to ketoacidosis due to pump malfunction, or problems with the cannula, needle, or insulin infusion set tubing resulting in cessation of insulin delivery
- Loss of communication between the pump and the sensor resulting in CGM values not being available to the user
- Catheter occlusion
- Catheter dislodgement or fracture during infusion set insertion
- Failures of the infusion set or at infusion site
- Mechanical or battery failures resulting in interruptions in insulin delivery or incorrect insulin delivery

Sensor breakage with fragments retained under the skin and catheter fracture during infusion set insertion are potential procedure-related complication. Based on post-market experience with similar devices and the results observed in this clinical study, the occurrence and severity of these events do not raise major concerns.

One potential risk of combining the CGM and the pump is that the user might be more inclined to use the CGM data in an unapproved way to determine their insulin dose. Inaccurate sensor results, if used to make dosing decisions, may lead to hypo or hyperglycemia as the CGM sensor has not been approved to be used to dose insulin. However, no further complications are expected due to the pump being combined with the CGM as a system beyond the potential complications of the pump or CGM alone.

Like other insulin pumps, there is an inherit risk that patients who do not use the system as instructed (nonadherence) could harm themselves. Patients should be informed that sensor interstitial glucose values should not be used to make insulin dose decisions and that all threshold alerts and alarms should be confirmed with a blood glucose measurement.

A pump malfunction may lead to a clinically significant hypoglycemic event, ketosis or ketoacidosis. A patient should respond with carbohydrate or insulin therapy, hydration, or other medical assistance as necessary. If unaddressed, severe hypoglycemia, severe hyperglycemia and ketoacidosis can result in serious harm and

death. Failure of the user to reset the insulin on board feature when indicated after a pump battery change may also lead to a clinically significant hypoglycemic event.

There is a risk of inadvertent insulin bolusing by young children playing with the buttons on the pump or by people rolling over in the night on the pump and inadvertently pushing the buttons on the pump. This pump contains an auto-locking feature to help mitigate accidental button pushing.

The risks of actions taken based on false positive hyperglycemic readings include inappropriate or excessive administration of insulin and failure to treat hypoglycemia. These inappropriate treatments could result in or prolong hypoglycemia and result in seizures, loss of consciousness, or death. The risks of actions taken based on false positive hypoglycemic readings include failure to administer insulin and failure to treat hyperglycemia. False positive high alerts and low alerts and alarms may increase the number of unplanned blood glucose checks; and disrupt patient activity and sleep. If the false positive rate is too high it can result in ‘alarm fatigue’ and patients may deactivate these alerts/alarms.

The risks of actions taken based on false negative hyperglycemic readings include failure to administer or insufficient administration of insulin and inappropriate administration of extra carbohydrate. These inappropriate treatments could prolong or induce hyperglycemia. The risks of actions taken based on false negative hypoglycemic readings include inappropriate administration of insulin or failure to administer or insufficient administration of extra carbohydrate. These inappropriate treatments could result in or prolong hypoglycemia and result in seizures, loss of consciousness, or death. False negative high alerts and low alerts and alarms will prevent the patient from having the opportunity to perform unplanned blood glucose tests and treat as instructed by their healthcare providers.

The CGM component is to be used only for tracking and trending glucose levels. The risk related to either an inaccurate sensor value outside of the patient’s normal range or a false alert or alarm is the risk of performing an unnecessary additional blood glucose test to confirm the erroneous sensor reading. The risk of medical harm may be mitigated through labeling which emphasizes that patients should confirm all CGM readings prior to making treatment decisions.

The risks are similar to the risks associated with the separate components.

C. Benefit-Risk Conclusions

The benefits of this Sensor Augmented Pump (SAP) is based on data collected in clinical studies and on the results of the current study that assessed its usability in children and adolescents between the ages of 8 and 17 as they are considered to be active managers. Children aged 2-7 would typically not manage pump use themselves, and their parents/caregivers would typically control their insulin dosing.

Additional factors to be considered in determining probable risks and benefits for this device are described in the following discussions. Children and adolescents with diabetes demonstrate frequent glucose excursions and are particularly vulnerable to both hyperglycemia and hypoglycemia. The use of self-monitored blood glucose (SMBG) values to manage diabetes is well-established, but traditional SMBG provides only a snapshot of one glucose value at a specific time. The use of continuous glucose monitoring (CGM) in children and adolescents provides an additional level of protection against hyper- and hypoglycemia and facilitates a more comprehensive understanding of glucose trends and patterns in response to activities of daily living as well as typical childhood stressors such as illness, erratic eating habits, and variable physical activity levels.

Benefits of an insulin pump include the ability to administer insulin in a manner that is more consistent with the normal physiologic release of insulin and that corresponds to specific needs and lifestyles. The insulin pump of the Animas Vibe system provides a method of insulin delivery that is more consistent with the physiologic release of insulin in a person without diabetes. Both basal and bolus rates of insulin release incorporate factors such as insulin sensitivity, age, weight, usual activity, and typical diet and can be individualized to each child or adolescent to maximize insulin effectiveness. The integration of a CGM with an insulin pump (sensor augmented pump (SAP) has the potential to assist children and adolescents and parents of very young children (2-7 years), children incapable of self-management, and newly diagnosed children and adolescents in the detection and prevention of glucose excursions, particularly, hyperglycemia and hypoglycemia. The amount of information provided by the sensor can also be used to inform treatment decisions and improve glycemic control.

Potential risks of combining the CGM and the pump is that the user might be more inclined to use the CGM data in an unapproved way to determine their insulin dose. Use of inaccurate glucose concentration data can result in an incorrect dose of insulin being delivered leading to hypo- or hyperglycemia. Another potential risk is that of young children deliberately or inadvertently altering insulin dosage/administration by pushing buttons or dislodging insulin infusion catheter and/or sensor.

- **Specific risks of the CGM and sensor include:**
 - Missed alerts, false negative and false positive alerts with corresponding actions or lack thereof.
 - Skin irritation or redness, inflammation, pain or discomfort, bruising, edema, rash, bleeding, infection, or allergic reaction due to either the sensor needle or the adhesive
 - Sensor breakage leaving a sensor fragment under the skin

- **Risks of the pump include the following:**
 - Tampering with pump buttons may result in inadvertent delivery of insulin resulting in hypoglycemia might occur more frequently with young children.

- Inadvertent dislodgement of insulin tubing from the infusion site might occur more frequently in children.
- Hypoglycemia from over-delivery of insulin due to a pump defect
- Cessation of or decreased insulin delivery resulting in hyperglycemia and possibly ketoacidosis due to pump failure, problems with the cannula, or insulin infusion set tubing, or failure of the user to reset the IOB feature after changing the pump battery. Catheter dislodgement or fracture during infusion set insertion resulting in injury and/or inability to administer insulin
- Mechanical or battery failures resulting in interruptions in insulin delivery or incorrect insulin delivery
- Catheter occlusion resulting in missed insulin dosing
- Skin irritation, or redness, inflammation, pain or discomfort, bruising, edema, rash bleeding, infection, or allergic reaction at the infusion site
- Failure of the infusion set or at the infusion site resulting in inability to administer insulin

Risks of the sensor augmented pump include both false positive and false negative readings with the following potential consequences:

- False positive hyperglycemic readings:
 1. Inappropriate or excessive administration of insulin and failure to treat hypoglycemia
 2. Loss of consciousness, seizures, or death related to severe or prolonged hypoglycemia.
- False positive hypoglycemic readings:
 1. Failure to administer insulin or a sufficient amount of insulin
 2. Failure to treat hyperglycemia.
- False positive high alerts and low alerts and alarms:
 1. Needless increase in SMBG
 2. Disruption of patient activity or sleep.
 3. Alarm fatigue with subsequent deactivation of alarms & alerts
- False negative hyperglycemic readings:
 1. Failure to administer or insufficient administration of insulin and inappropriate administration of CHOs, thus increasing the risk of prolonging or inducing/exacerbating hyperglycemia.
- False negative hypoglycemic readings:
 1. Inappropriate administration of insulin
 2. Failure to administer or insufficient administration of extra carbohydrate.
 3. Inappropriate treatments could result in or prolong hypoglycemia and result in seizures, loss of consciousness, or death.
- False negative high alerts and low alerts and alarms:
 1. Failure to recognize need to intervene with additional SMBG and indicated interventions.
- Use of sensor values, alarms or alerts

1. Have the potential to alert users to glucose values outside their target range
2. Are especially valuable in individuals who have hypoglycemic unawareness or do not recognize the signs and symptoms of hyperglycemia.
3. Inaccurate alarms and alerts may increase the risk of performing unnecessary capillary glucose measurements.

The risks of the device failing to alert an asymptomatic user to a high or low blood sugar is no greater than that associated with traditional blood glucose monitoring. Moreover, the sponsor has mitigated the risk of inappropriate interventions and severe adverse events (SAEs) through labeling that emphasizes patients should obtain capillary glucose measurements to confirm all CGM readings prior to making treatment decisions.

Every insulin delivery method carries some degree of risk of a harmful event. However, health care providers (HCPs) generally will not prescribe insulin pumps to patients or parents/caregivers who do not demonstrate that they are checking glucose levels frequently (4-6 times/day), can recognize and treat the symptoms of both hypo- and hyperglycemia, and have some knowledge of sick day “rules”. Likewise, HCPs are not likely to prescribe sensors or sensor-augmented pumps to patients or parents/caregivers who are not engaged in care, demonstrate adequate self-management/management skills and willingness to perform finger stick blood glucose measurements twice daily for sensor calibration, and/or are seeking ways to improve glycemic control.

Adolescents often have high risk behaviors or developmental tasks, e.g. acceptance by peers, which may interfere with self-management skills regardless of insulin delivery method. The use of an insulin pump, however, can be programmed with basal rates that can limit the severity of hyperglycemia, thus preventing diabetic ketoacidosis (DKA). Pre-set pump settings can also insure that basal rates and bolus doses do not exceed the recommended total daily dose (TDD), thus reducing the risk of hypoglycemia. Therefore, although non-adherence to instructions and misuse of the pump or pump malfunction has the potential to result in hypo- or hyperglycemia, the pump has built in features that can mitigate these risks.

Additional safeguards which include pre-set pump settings, activating an auto lock feature which would prevent additional boluses or changes to pre-set settings, documentation of basal and bolus amounts of insulin delivered {TDD}, placement of infusion sites and sensors in sites that are out of reach, adequately securing the infusion site and tubing, and placing the device in pump “packs”) can reduce the risk of deliberate or inadvertent tampering with device or insertion sites that may result in over or under-delivery of insulin in children or dislodgment of the tubing from the insertion site.

There is a risk of inadvertent insulin bolusing by children playing with the buttons on the pump or by people rolling over in the night on the pump and inadvertently

pushing the buttons on the pump. This pump contains a locking feature, which will prevent accidental button pushing; however, this feature must be enabled.

Pediatric participants demonstrated competency following training and were able to complete respective tasks, which were assigned in a safe and efficacious manner, while also acknowledging, that the simulation may have impacted decision-making when there was a use event, as the same course of action would not have been performed when connected to the pump in real life. Participants who experienced difficulty were able to recover from their use events either on their own or with help from their caregiver. Thereby preventing subsequent patient harm. Additional risks are mitigated by careful patient selection and education. Only patients/parents/caregivers that are willing to perform the necessary blood glucose checks, sensor changes and calibrations should be prescribed the system. Training should include verification that patients understand the principles and use of specific devices and provide satisfactory return demonstrations of manual tasks.

Risk mitigations associated with use of insulin pump therapy include labeling and training with a healthcare provider who has been certified as a pump/CGM trainer. Risk mitigations that would prevent children, especially young children, from altering basal and bolus rates should include an auto-locking feature after setting basal rates and bolus doses, securing the infusion site and tubing, and securing the pump in either a tamper resistant case or beyond the reach of the child. Additional risk mitigations include labeling that emphasizes the potential risk of and strategies to reduce the risk of inadvertent or deliberate tampering with pump settings. Users are also instructed to have a backup plan for therapy (e.g. insulin pen or syringe) in case they are unable to use their pump.

The sponsor revised the Owner's Booklet to reflect the changes made to extend the use of the Animas Vibe System to include patients between the ages of 2 and 17 years old. Specifically, the sponsor included language to make more prominent the risks associated with the use of the system in pediatric patients aged 2-7 and 8-17 years old. Additionally, the sponsor included more prominent language cautioning that the insulin on board (IOB) will revert back to zero (0) when the battery is changed (so that users will know to re-enter that value).

The labeling and the receiver display the following warnings regarding use of this system in the pediatric population:

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

Despite the reduced accuracy in this patient population, particularly in the low glucose concentration range, the CGM provides valuable tracking and trending information to children and their parents. If the expected performance of the device is understood, the beneficial information gained from this device outweighs the risk of missed low glucose alerts. Therefore, the strong warnings added to the labeling and receiver display explaining the differences in performance in pediatrics compared to adults and warning against relying solely on CGM alerts to detect low glucose help to mitigate the risks of poor performance.

The sponsor has determined that the language in the labeling is consistent with an 8th grade reading level. The sponsor states that some parts in the section on Basal Insulin, may present a challenge to many children and adolescents who are active managers of their diabetes particularly with respect to having up to 4 basal program and 12 basal rates in 24 hours. This section is emphasized in the training on the use of this device.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks of this device.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The benefits of using the Animas Vibe System outweigh the risks.

XIII. CDRH DECISION

CDRH issued an approval order on December 24, 2015. The final conditions of approval cited in the approval order are described below.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.