Manufacturer report: Malfunction

[redacted]

reporter occupation: 305 PATIENT
MAUDE link: XXXXXXXXXXXXXXXXXX

dates

Report Date: [redacted]
Event Date: [redacted]
Mfr Rec'd Date: [redacted]
FDA Rec'd Date: [redacted]
Date Added: [redacted]
Date Changed: [redacted]

device

- **product code:** OYC
- **device name:** Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor
- **brand:** [redacted]
- **generic:** INSULIN INFUSION PUMP / SENSOR AUGMENTED
- **operator:** 0LP LAY USER/PATIENT
- **model #:** [redacted]
- **catalog #:** [redacted]
- **lot #:**
- **other ID #:**
- **evaluated by manufacturer:** Y
- **available:** R
- **expires:**
- **PMA/510K #:**

description

THE CUSTOMER REPORTED VIA PHONE CALL THAT THE PUMP HAD MOTOR ERROR ALARM AND MOTOR POSITION ENCODER ERROR ALARM. THE BLOOD GLUCOSE AT THE TIME OF THE INCIDENT WAS 229 MG/DL. THE CUSTOMER WAS ADVISED THAT THE INSULIN PUMP WILL NEED TO BE REPLACED. THE CUSTOMER WAS ADVISED TO DISCONNECT FROM THE INSULIN PUMP AND REVERT TO BACK-UP PLAN. TROUBLESHOOTING WAS NOT ABLE TO RESOLVE THE ISSUE. THE DEVICE WILL BE RETURNED FOR ANALYSIS.

other elements

- mdr-report-key : [redacted]
- report-number: [redacted]
- manufacturer-link-flag-: Y
- adverse-event-flag: N
- product-problem-flag: Y
- date-report: [redacted]

- date-of-event: [redacted]
- reprocessed-and-reused-flag: N
- health-professional: N
- date-manufacturer-received: [redacted]
- single-use-flag: N
- previous-use-code: U
- date-added: [redacted]
- date-changed: [redacted]
- event-type: M
- event-type-description: Malfunction
- report-source-code: M
- report-source-description: Manufacturer report
- reporter-occupation-code: 305
- reporter-occupation-description: PATIENT
- initial-report-to-fda: U
- initial-report-to-fda-description: Unknown
- report-to-fda: *
- report-to-fda-description: No answer provided
- event-location: I
- name: [redacted]
- original-name: [redacted]
- street-1: [redacted]
- city: [redacted]
- state-code: [redacted]
- zip-code: [redacted]
- zip-code-ext: [redacted]
- country-code: [redacted]
- postal-code: [redacted]
- text: ANALYSIS FOUND THE UNIT WITH STUCK MOTOR ERROR ALARM LOOP DURING BOLUS DELIVERY AND MOTOR POSITION ENCODER ERROR ALARM WAS CONFIRMED IN HISTORY FILE. HOWEVER, THE UNIT PASSED REWIND, BASIC OCCLUSION, PRIME AND DISPLACEMENT TESTS. THE MOTOR WAS TESTED OUTSIDE OF THE DEVICE AND PASSED THE MOTOR TEST. THE MOTOR MAY HAVE HAD INTERMITTENT FAILURE THAT WAS NOT DETECTED DURING TESTING. NOTE: THIS IS A REMEDIATION MDR. [redacted] IMPLEMENTED REVISED MDR REPORTABILITY CRITERIA EFFECTIVE ON [redacted]. SUBSEQUENTLY, [redacted] CONDUCTED A ONE YEAR RETROSPECTIVE REVIEW OF COMPLAINTS. THIS EVENT WAS RETROSPECTIVELY IDENTIFIED TO BE REPORTABLE BASED ON THE REVISED MDR REPORTABILITY CRITERIA. (B)(4).
- text: THE CUSTOMER REPORTED VIA PHONE CALL THAT THE PUMP HAD MOTOR ERROR ALARM AND MOTOR POSITION ENCODER ERROR ALARM. THE BLOOD GLUCOSE AT THE TIME OF THE INCIDENT WAS 229 MG/DL. THE CUSTOMER WAS ADVISED THAT THE INSULIN PUMP WILL NEED TO BE REPLACED. THE CUSTOMER WAS ADVISED TO DISCONNECT FROM THE INSULIN PUMP AND REVERT TO BACK-UP PLAN. TROUBLESHOOTING WAS NOT ABLE TO RESOLVE THE ISSUE. THE DEVICE WILL BE RETURNED FOR ANALYSIS.
- device-sequence-no: 1.0
- date-received: [redacted]
- brand-name: [redacted]
- generic-name: INSULIN INFUSION PUMP / SENSOR AUGMENTED
- model-number: [redacted]
- catalog-number: [redacted]
- device-availability: R
- date-returned-to-manufacturer: [redacted]
- device-evaluated-by-manufactur: Y

- device-operator: 0LP
- device-operator-description: LAY USER/PATIENT
- device-report-product-code: OYC
- device-name: Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor
- review-panel-code: CH
- review-panel-description: Clinical Chemistry
- device-class-code: 3
- device-class-description: Devices subject to General Controls, Special Controls, and Premarket Clearance
- third-party-review-eligible-code: N
- third-party-review-eligible-description: Not Eligible for Accredited Persons Program
- submission-type-code: 2
- submission-type-description: PMA
- patient-sequence-number: 1
- date-received: [redacted]
- sequence-number-outcome: 8.