Manufacturer report: Death

[redacted]

reporter occupation: 0HP HEALTH PROFESSIONAL
MAUDE link: XXXXXXXXXXXXXXXXXXXX

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:** [redacted]
- **operator:** [redacted]
- **model #:** [redacted]
- **catalog #:** [redacted]
- **lot #:**
- **other ID #:** XXXXXXXXXXXXXXXXXXX
- **evaluated by manufacturer:** R
- **available:** N
- **expires:**
- **PMA/510K #:**

description

IT WAS REPORTED THAT THE CUSTOMER PASSED AWAY. CAUSE OF DEATH WAS DUE TO DIABETIC KETOACIDOSIS (DKA). DUE TO INSURANCE ISSUES, THE CUSTOMER WAS UNABLE TO MAINTAIN ADEQUATE SENSOR SUPPLIES. THE CUSTOMER WAS UNDERGOING DIALYSIS AND DUE TO THE LACK OF SENSOR SUPPLIES, THE CUSTOMER WAS UNABLE TO MANAGE CHANGING INSULIN NEEDS DURING DIALYSIS, AND SUBSEQUENTLY WENT INTO DKA AND WAS HOSPITALIZED. THE PATIENT LOST A DEGREE OF COGNITIVE FUNCTIONING WITH DKA AND THE HEALTHCARE PROVIDER DECIDED TO DISCONTINUE PUMP THERAPY WHILE HOSPITALIZED. THE CUSTOMER WAS DISCHARGED FROM HOSPITALIZATION WITH MANUAL INJECTIONS AND THE HCP WAS MONITORING THE PATIENT BEFORE AND AFTER DISCHARGE. HOWEVER, THE CUSTOMER ULTIMATELY PASSED AWAY DUE TO DKA. THE CUSTOMER WAS NOT USING THE PUMP AT THE TIME OF DEATH.

other elements

- mdr-report-key: [redacted]
- report-number: [redacted]
- manufacturer-link-flag-: Y
- adverse-event-flag: Y
- product-problem-flag: N
- date-report: [redacted]
- date-of-event: [redacted]
- reprocessed-and-reused-flag: N
- health-professional: Y
- date-manufacturer-received: [redacted]
- device-date-of-manufacture: [redacted]
- single-use-flag: N
- previous-use-code: R
- date-added: [redacted]
- date-changed: [redacted]
- event-type: D
- event-type-description: Death
- report-source-code: M
- report-source-description: Manufacturer report
- reporter-occupation-code: 0HP
- reporter-occupation-description: HEALTH PROFESSIONAL
- initial-report-to-fda: U
- initial-report-to-fda-description: Unknown
- report-to-fda: *
- report-to-fda-description: No answer provided
- type-of-report: I
- type-of-report-description: Initial submission
- source-type: HEALTH PROFESSIONAL
- source-type-description: HEALTH PROFESSIONAL
- event-location: I
- name: [redacted]
- original-name: [redacted]
- address-1: [redacted]
- city: [redacted]
- state-code: [redacted]
- zip-code: [redacted]
- country-code: [redacted]
- postal-code: [redacted]
- text: NO PRODUCT WAS RETURNED FOR EVALUATION. SHOULD NEW RELEVANT INFORMATION BECOME AVAILABLE, A SUPPLEMENTAL REPORT WILL BE SUBMITTED. DEVICE NOT RETURNED.
- text: IT WAS REPORTED THAT THE CUSTOMER PASSED AWAY. CAUSE OF DEATH WAS DUE TO DIABETIC KETOACIDOSIS (DKA). DUE TO INSURANCE ISSUES, THE CUSTOMER WAS UNABLE TO MAINTAIN ADEQUATE SENSOR SUPPLIES. THE CUSTOMER WAS UNDERGOING DIALYSIS AND DUE TO THE LACK OF SENSOR SUPPLIES, THE CUSTOMER WAS UNABLE TO MANAGE CHANGING INSULIN NEEDS DURING DIALYSIS, AND SUBSEQUENTLY WENT INTO DKA AND WAS HOSPITALIZED. THE PATIENT LOST A DEGREE OF COGNITIVE FUNCTIONING WITH DKA AND THE HEALTHCARE PROVIDER DECIDED TO DISCONTINUE PUMP THERAPY WHILE HOSPITALIZED. THE CUSTOMER WAS DISCHARGED FROM HOSPITALIZATION WITH MANUAL INJECTIONS AND THE HCP WAS MONITORING THE PATIENT BEFORE AND AFTER DISCHARGE. HOWEVER, THE CUSTOMER ULTIMATELY PASSED AWAY DUE TO DKA. THE CUSTOMER WAS NOT USING THE PUMP AT THE TIME OF DEATH.
- device-sequence-no: 1.0

- date-received: [redacted]
- brand-name: [redacted]
- generic-name: [redacted]
- model-number: [redacted]
- catalog-number: [redacted]
- other-id-number: [redacted]
- device-availability: N
- device-evaluated-by-manufactur: R
- 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: [redacted]