Report date: *4/6/2024 8:16:22 PM* *SW version: 1.1*

Open FDA query:

https://api.fda.gov/device/event.json?search=date_received:[20200101+TO+20240315]+AND+device.device_report_product_code:(FMF)&sort=date_received:desc&limit=3

Query results: *3*

Report generation time: *0min 29sec*

Overview

Product Problems	MDR Counts	Problem Summaries
Patient Device Interaction Problem	1	The INPEN device experienced a screw movement issue; preventing the injection of insulin when the dose button was pressed; resulting in hyperglycemia in a patient with a blood glucose reading of 380 mg/dL.
Failure to Deliver	1	A malfunctioning NOVOPEN 5 insulin delivery device prevented a patient from injecting medication; causing anxiety and ultimately leading to a heart attack. The device's delivery system issue hindered the patient's ability to push out the medication liquid.
Excess Flow or Over-Infusion	1	A patient received an extra unit of insulin from a Novo Nordisk INPEN MMT-105NNBLNA NOVO NORDISK BLUE device. The device was not returned for analysis; leaving it uncertain whether the device malfunctioned or if there was user error.

Product Problems	MDR References	Patient Problems
Patient Device Interaction Problem	3012822846-2024-00345	["Hyperglycemia"]
Failure to Deliver	9681821-2024-00042	["Myocardial Infarction"]
Excess Flow or Over-Infusion	3012822846-2024-00347	["No Clinical Signs; Symptoms or Conditions"]

Product Problems	Manufacturers	Device Brands
Patient Device Interaction Problem	COMPANION MEDICAL INC	INPEN MMT-105ELGYNA ELI LILY GRAY
Failure to Deliver	NOVO NORDISK A/S	NOVOPEN 5
Excess Flow or	COMPANION MEDICAL INC	INPEN MMT-105NNBLNA NOVO NORDISK

Over-Infusion		BLUE

Product Problems	Similarity Score
Patient Device Interaction Problem	Similarity Score: 0% Explanation: The two problems are not similar. The first problem is about a nurse being stuck with a used needle after attempting to engage the safety mechanism. The second problem is about a customer experiencing hyperglycemia with a blood glucose reading value of 380 mg/dL treated with manual injection/insulin pen.
Failure to Deliver	Similarity score: 0% The two problems are not similar. The first problem is about a nurse who was stuck with a used needle after attempting to engage the safety mechanism. The second problem is about a customer who was anxious; which caused a heart attack.
Excess Flow or Over-Infusion	Similarity Score: 0% Explanation: The two problems are not similar. The first problem is about a nurse being stuck with a used needle after attempting to engage the safety mechanism. The second problem is about an InPen delivering one unit extra.

Summary of Related Manufacturers and Device Brands

Manufacturers	Device Brands
- COMPANION MEDICAL INC: 2 - NOVO NORDISK A/S: 1	- INPEN MMT-105ELGYNA ELI LILY GRAY: 1 - NOVOPEN 5: 1 - INPEN MMT-105NNBLNA NOVO NORDISK BLUE: 1

Complaint Reportability Assessment:

Top Matching Problem Reports
1. Report 1
* Similarity: 75%
* Product Problem: Patient Device Interaction Problem
* Device Brand Name: INPEN MMT-105ELGYNA ELI LILY GRAY
* Patient Problem: Hyperglycemia
* Device Manufacturer: COMPANION MEDICAL INC
* Report Number: 3012822846-2024-00345

* Explanation: Both reports involve a problem with an insulin delivery device. In both cases; the device malfunctioned; causing the patient to receive an incorrect dose of insulin.
2. Report 2
* Similarity: 70%
* Product Problem: Failure to Deliver
* Device Brand Name: NOVOPEN 5
* Patient Problem: Myocardial Infarction
* Device Manufacturer: NOVO NORDISK A/S
* Report Number: 9681821-2024-00042
* Explanation: Both reports involve a problem with an insulin delivery device. In both cases; the device malfunctioned; causing the patient to receive an incorrect dose of insulin.
3. Report 3
* Similarity: 65%
* Product Problem: Excess Flow or Over-Infusion
* Device Brand Name: INPEN MMT-105NNBLNA NOVO NORDISK BLUE
* Patient Problem: No Clinical Signs; Symptoms or Conditions
* Device Manufacturer: COMPANION MEDICAL INC
* Report Number: 3012822846-2024-00347
* Explanation: Both reports involve a problem with an insulin delivery device. In both cases; the device malfunctioned; causing the patient to receive an incorrect dose of insulin.

Supporting Data

{{{DataAggregate}}} 1-1:

1. {{{DataIndex}}} 1:

product_problems:["Patient Device Interaction Problem"]

device.brand_name:INPEN MMT-105ELGYNA ELI LILY GRAY

patient.patient_problems:["Hyperglycemia"]

device.manufacturer_d_name:COMPANION MEDICAL INC

report_number:3012822846-2024-00345

mdr_text.text:CURRENTLY IT IS UNKNOWN WHETHER OR NOT THE DEVICE MAY HAVE CAUSED OR CONTRIBUTED TO THE EVENT AS NO PRODUCT HAS BEEN RETURNED. THE DEVICE WILL BE RETURNED FOR ANALYSIS AND FURTHER INFORMATION WILL FOLLOW ONCE THE ANALYSIS HAS BEEN COMPLETED. NO CONCLUSION CAN BE DRAWN AT THIS TIME. MEDTRONIC, INC. (MEDTRONIC) IS SUBMITTING THIS REPORT TO COMPLY WITH 21 C.F.R. PART 803, THE MEDICAL DEVICE REPORTING REGULATION. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION IN THE TIME ALLOTTED AND HAS PROVIDED AS MUCH INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEES CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY "DEFECTS" OR HAS "MALFUNCTIONED". THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA, TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REPORTING PURSUANT TO PART 803. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE IT BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

INFORMATION RECEIVED BY MEDTRONIC INDICATED THAT THE CUSTOMER EXPERIENCED HYPERGLYCEMIA WITH A BLOOD GLUCOSE READING VALUE OF 380 MG/DL TREATED WITH MANUAL INJECTION/INSULIN PEN. IT WAS ALSO REPORTED THAT THE INPEN HAD SCREW MOVEMENT ISSUE. TROUBLESHOOTING WAS PERFORMED AND IDENTIFIED INPEN SCREW DID NOT MOVE WHEN INJECTION/DOSE BUTTON WAS PUSHED. NO HARM REQUIRING MEDICAL INTERVENTION WAS REPORTED. THE CUSTOMER WILL DISCONTINUE USE OF THE DEVICE AND A INPEN WILL BE REPLACED. THE INPEN WILL BE RETURNED FOR FAILURE ANALYSIS.

Similarity: 75%

Explanation: Both reports involve a problem with an insulin delivery device. In both cases, the device malfunctioned, causing the patient to receive an incorrect dose of insulin.

2. {{{DataIndex}}} 2:

product_problems:["Failure to Deliver"]

device.brand_name:NOVOPEN 5

patient.patient_problems:["Myocardial Infarction"]

device.manufacturer_d_name:NOVO NORDISK A/S

report_number:9681821-2024-00042

mdr_text.text:THE CUSTOMER WAS ANXIOUS, WHICH CAUSED HEART ATTACK. [MYOCARDIAL INFARCTION]. SOMETIMES THE MEDICATION LIQUID COULDN'T BE PUSHED OUT [DEVICE DELIVERY SYSTEM ISSUE]. CASE DESCRIPTION: THIS SERIOUS SPONTANEOUS CASE FROM CHINA WAS REPORTED BY A CONSUMER AS "THE CUSTOMER WAS ANXIOUS, WHICH CAUSED HEART ATTACK.(HEART ATTACK)" BEGINNING ON (B)(6) 2024, "SOMETIMES THE MEDICATION LIQUID COULDN'T BE PUSHED OUT(DEVICE DELIVERY SYSTEM ISSUE)" WITH AN UNSPECIFIED ONSET DATE, AND CONCERNED A 80 YEARS OLD PATIENT WHO WAS TREATED WITH NOVOPEN 5 (INSULIN DELIVERY DEVICE) FROM UNKNOWN START DATE FOR "DEVICE THERAPY." PATIENT'S HEIGHT, WEIGHT AND BMI (BODY MASS INDEX) WERE NOT REPORTED. DOSAGE REGIMENS: NOVOPEN 5: MEDICAL HISTORY WAS NOT PROVIDED. CONCOMITANT PRODUCTS INCLUDED - INSULIN. ON (B)(6) 2024, IT WAS REPORTED THAT WHEN A CUSTOMER USED NOVOPEN 5, SOMETIMES THE MEDICATION LIQUID COULDN'T BE PUSHED OUT. IN THE PREVIOUS NIGHT, THE PATIENT THOUGHT THE PEN HAD A PROBLEM. THE MEDICATION LIQUID COULDN'T BE PUSHED OUT AND THE INSULIN COULDN'T BE INJECTED. THE PATIENT WAS ANXIOUS, WHICH CAUSED HEART ATTACK. THE NAME OF THE DRUG STORE WAS PROVIDED. THE PATIENT'S TWO PIECES OF NOVOPEN COULD BE USED NORMALLY. BATCH NUMBER OF NOVOPEN 5 WAS REQUESTED. ACTION TAKEN TO NOVOPEN 5 WAS NOT REPORTED. THE OUTCOME FOR THE EVENT "THE CUSTOMER WAS ANXIOUS, WHICH CAUSED HEART ATTACK.(HEART ATTACK)" WAS NOT REPORTED. THE OUTCOME FOR THE EVENT "SOMETIMES THE MEDICATION LIQUID COULDN'T BE PUSHED OUT(DEVICE DELIVERY SYSTEM ISSUE)" WAS RECOVERED. "THIS REPORT IS FOR A FOREIGN DEVICE THAT IS ASSESSED AS "SIMILAR" TO US MARKETED NOVOPEN ECHO".

Similarity: 70%

Explanation: Both reports involve a problem with an insulin delivery device. In both cases, the device malfunctioned, causing the patient to receive an incorrect dose of insulin.

3. {{{DataIndex}}} 3:

product_problems:["Excess Flow or Over-Infusion"]

device.brand_name:INPEN MMT-105NNBLNA NOVO NORDISK BLUE

patient.patient_problems:["No Clinical Signs, Symptoms or Conditions"]

device.manufacturer_d_name:COMPANION MEDICAL INC

report_number:3012822846-2024-00347

mdr_text.text:CURRENTLY IT IS UNKNOWN WHETHER OR NOT THE DEVICE MAY HAVE CAUSED OR CONTRIBUTED TO THE EVENT AS NO PRODUCT HAS BEEN RETURNED. NO CONCLUSION CAN BE DRAWN AT THIS TIME. WE THEREFORE CONSIDER THIS REPORT COMPLETE TO THE BEST OF OUR KNOWLEDGE. MEDTRONIC, INC. (MEDTRONIC) IS SUBMITTING THIS REPORT TO COMPLY WITH 21 C.F.R. PART 803, THE MEDICAL DEVICE REPORTING REGULATION. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION IN THE TIME ALLOTTED AND HAS PROVIDED AS MUCH INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEES CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY "DEFECTS" OR HAS "MALFUNCTIONED". THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA, TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REPORTING PURSUANT TO PART 803. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE IT BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

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Similarity: 65%

Explanation: Both reports involve a problem with an insulin delivery device. In both cases, the device malfunctioned, causing the patient to receive an incorrect dose of insulin.

Raw Data

{{datachunk}}product_problems:["Patient Device Interaction Problem"]

device.brand_name:INPEN MMT-105ELGYNA ELI LILY GRAY

patient.patient_problems:["Hyperglycemia"]

device.manufacturer_d_name:COMPANION MEDICAL INC

report_number:3012822846-2024-00345

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{{datachunk}}product_problems:["Failure to Deliver"]

device.brand_name:NOVOPEN 5

patient.patient_problems:["Myocardial Infarction"]

device.manufacturer_d_name:NOVO NORDISK A/S

report_number:9681821-2024-00042

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{{datachunk}}product_problems:["Excess Flow or Over-Infusion"]

device.brand_name:INPEN MMT-105NNBLNA NOVO NORDISK BLUE

patient.patient_problems:["No Clinical Signs, Symptoms or Conditions"]

device.manufacturer_d_name:COMPANION MEDICAL INC

report_number:3012822846-2024-00347

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Configuration Data

https_url1: api.fda.gov/device/event.json?

limit1: 3

KEYWORD1-SEARCH:

SORT1-FIELD: date_received

SORT1-TERM: desc

COUNT1-FIELD:

COUNT1-TERM:

data1_fields: product_problems, device.brand_name, patient.patient_problems, device.manufacturer_d_name, report_number, mdr_text.text

report_title: Complaint Reportability Assessment

AI-WordsPerReport: 1500

AI-ModelMaxOutputTokens: 2048

AI-ModelTemperature: 0.05

AI-ModelTopP: 0.4

AI-ModelTopK: 10

AI-MDRSimilarityPrompt: Match the most similar problem reports to this ({{problem_input}}). Include all important details. Include all reference numbers. Include the similarity scores as a percentage. Explain the similarities. Use semantic similarity measurements. Present results in descending similarity scores. For each matching result

AI-ProblemSummaryPrompt: Describe the following product problem in a couple of sentences. Include essential details.

AI-ReportSummaryPrompt: List the top matching problem reports with the highest similarity scores. Include all details about the matching problems.

AI-CountSummaryPrompt: List each unique item along with the count for each item.

AI-ProblemSimilarityPrompt: Analyze the similarity of this problem ({{problem_input}}) to the following problem. Use semantic similarity measurement. Present the result with the similarity score as a percentage followed by a concise explanation of the similarity score.

SEARCH1-FIELDS:

{ date_received: [20200101+TO+20240315], device.device_report_product_code: (FMF)}