From FDA MAUDE DATA BASE: A sample of patient injuries from Lifting Devices Voluntarily Reported to FDA 2017-2018

I. ARJOHUNTLEIGH MAGOG INC. LIFT, PATIENT, NON-AC-POWERED

Device Problem**:** No Known Device Problem
Event Type: Injury

Event Description: On (b)(6) 2018, it was reported that the homecare patient was severely injured during use a arjo floor lift. More information is unavailable at this time.

Manufacturer Narrative: (b)(4). Additional information will be provided upon conclusions of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7636780&pc=FSA

II. APEX HEALTHCARE MFG INC HOYER PRESENCE ELECTRIC PATIENT LIFT

Model Number: HOY-PRESENCE
Event Date: 06/03/2018
Device Problem: No Known Device Problem
Event Type: Injury

Event Description: It was reported to the manufacturer by the end user, per the end user, "the staff had resident in sling. They were transferring her from bed to wheelchair. Lift got stuck. She kept trying to put it down. It allegedly started to tilt. They were able to lower it down to the floor with resident in it. The following injuries allegedly occurred: cut on her arm, foot was swollen. They did an x-ray, no fractures. The product has been taken out of use. " numerous requests to this facility have been made to receive additional information and details related to this alleged incident report with no response from the facility. (b)(4) were entered into our system to have the lift returned to joerns for investigation. As of this writing, the lift has not been returned.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7626963&pc=FSA

III. APEX HEALTHCARE MFG INC HOYER PRESENCE ELECTRIC PATIENT LIFT

Model Number: HOY-PRESENCE-S
Device Problem: Inadequate training
Event Date :06/07/2018
Event Type: Injury

Event Description: It was reported to the manufacturer by the end user, per the end user, "a fall that they had while using a hoyer presence. " upon speaking to the facility, the resident fell out of the sling while being moved in the lift. When the resident was picked-up, the strap came off the cradle. The resident fell out of the sling backwards, head first. The resident was sent to the hospital via 911 and sustained a laceration to the left back side of the head that required 8 staples. Complaint (b)(4) was entered into our system.

Manufacturer Narrative: The facilities maintenance repaired the lift prior to notifying the manufacturer of the incident.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7605676&pc=FSA

IV. INVACARE TAYLOR STREET HEAVY DUTY POWER LIFT PLUS LIFT, PATIENT, NON-AC-POWERED

Model Number: RPA600-1
Device Problem: Unintended movement
Event Date: 04/05/2018
Event Type: Injury

Event Description: The dealer reported that the patient was being transferred from a bed to a wheelchair, and her back and bottom were in the chair, when the rpa600-1 lift tipped forward and the swivel bar hit her in the head. The dealer stated that the patient was sent to the hospital where she received x-rays and a ct scan, and it was determined that she had sustained a bruise to her forehead and a neck fracture.

Manufacturer Narrative: A follow-up call was made to the facility where the incident occurred. The facility administrator advised that there were three therapists involved when the incident happened. The patient was dropped about 2 inches into the chair, which is when the boom came forward and hit her in the head. He advised that the sling was still attached to the swivel bar when the patient dropped down into the chair, but he was not aware of what model sling was being used. He was not able to provide the patient's weight but claimed that she was well within the weight capacity of the lift. He stated that when the event happened, they were aware that the patient had sustained a bruise to her forehead but they did not think it was anything more severe until about 20 minutes later when she had slurred speech. It was then that they took her to the hospital where the neck fracture was discovered. He did not know if it the fracture preexisted the incident, just that it was discovered as a result of the incident. He was also not aware of what medical treatment the patient received, but he advised that she is back at the facility and is doing well. The facility administrator stated that he was not sure that there was a device malfunction. He stated that they tried to re-create the incident the next day but were unable to do so. He advised that after much discussion, it was determined that the wheels of the lift were locked at the time of the incident. He stated that they were not aware that the wheels should not be locked during transfer, and he advised that after doing an internal investigation, they feel that having the wheels locked could be what caused the lift to tip over. He also stated that a representative from the state came out and performed an inspection, and it was noted that the facility was not transferring patients properly; there was no documented defect/malfunction with the lift. Following the incident, the lift was removed from service. A replacement rpl600-1 lift was sent to the facility, as the rpa600-1 lift has been discontinued, and the dealer did an in-service at the facility to retrain the staff and ensure that they understand how to properly operate the lift. The rpa600-1 owner's manual, as well as labeling on the lift, states, "do not lock the casters of the patient lift when lifting an individual. Casters must be left unlocked to allow patient lift to stabilize during lifting procedures. " additionally, the manual warns that when positioning the lift, to be aware of the position of the swivel bar and the patient. On (b)(6) 2018, the lift was returned to invacare and it is pending an evaluation. Once completed, a supplemental record will be filed.

V. INVACARE TAYLOR STREET INVACARE RELIANT 450 BATTERY-POWERED LIFT LIFT, PATIENT, NON-AC-POWERED

Model Number: RPL450-1
Device Problem: Unintended movement
Event Type: Injury

Event Description: The facility reported that the motor on the rpl450-1 lift failed, causing the patient to fall to the floor. She sustained a large laceration to the left lower extremity, which required 72 sutures.

Manufacturer Narrative: The facility advised that two stnas (state tested nursing assistants) were in the process of transferring the patient when the incident occurred. The patient was approximately 1-2 inches away from the bed and 1-2 inches above the height of the bed when the boom lowered. The reported weight of the patient is (b)(6), which is within the weight capacity of 450 pounds for the rpl450-1 lift. On (b)(6) 2018, an invacare technician went to the facility to service the lift. He advised that the gears were stripped within the actuator motor, which controls the raising and lowering of the boom. The invacare technician advised that the facility had just signed up for invacare's preventative maintenance program, and this was the first time that an invacare technician had serviced the lift. The date code of the actuator indicates that it is original to the lift and has exceeded its wear period of 2 years. Additionally, the rpl450-1 lift, which was manufactured in april 2001, has exceeded its expected life of 8 years. The invacare technician replaced the actuator to restore function of the lift. He brought the defective actuator back to invacare, and it is pending further analysis. Once the evaluation has been completed, a supplemental record will be filed.

VI. INVACARE TAYLOR STREET HEAVY DUTY POWER LIFT PLUS LIFT, PATIENT, NON-AC-POWERED

Model Number RPA600-1
Device Problem Unintended movement
Event Date 04/05/2018
Event Type Injury

Event Description: The dealer reported that the patient was being transferred from a bed to a wheelchair, and her back and bottom were in the chair, when the rpa600-1 lift tipped forward and the swivel bar hit her in the head. The dealer stated that the patient was sent to the hospital where she received x-rays and a ct scan, and it was determined that she had sustained a bruise to her forehead and a neck fracture.

VII. APEX HEALTHCARE MFG INC HOYER STATURE PATIENT LIFT

Model Number: HOY-STATUREWSC
Device Problem: Device operates differently than expected
Event Date: 04/17/2018
Event Type: Injury

Event Description: It was reported to the manufacturer by the end user, per the end user, hoyer stature lift failed and cradle fell to floor with resident in sling yesterday. Resident was injured and went to hospital but is back at facility. Upon speaking with the facility, it was stated that "resident was transferred from motorized wheelchair to her bed. The mast fell and the resident landed on the floor. Resident was in hoyer sling. Resident was transferred via 911 to hospital to the er for evaluation. X-rays and ct-scan were performed. Resident sustained bruise on right shoulder, bruise to right forehead (right above the eye) and bump to the back of the head (center of head). Complaint# (b)(4) were entered into our system to have the lift returned to joerns for investigation. As of this writing, the lift has not been returned.

VIII. APEX HEALTHCARE MFG INC HOYER HPL402 LIFT PATIENT LIFT

Model Number HPL402
Device Problems Inadequate training; Device handling issue
Event Date 03/28/2018
Event Type Injury

Event Description: It was reported to the manufacturer by the end user, per the end user, patient arrived for regular scheduled dialysis treatment via wheelchair with nursing home hoyer sling pad placed under patient. Upon patient transfer from the wheelchair to the dialysis chair utilizing the joerns hoyer lift device with the nursing home hoyer sling pad, the patient fell backwards partially out of the hoyer sling pad. The patient hit his head landing on a staff member's foot and the floor. Patient did not lose consciousness. Patient complained of head and upper back pain. The 911 was called and patient was transferred and admitted to the hospital with a sub-arachnoid hemorrhage and fracture of left 6th rib. Upon speaking to the facility staff, it was mentioned that the sling was positioned half way down on the patient's back. After the incident, the biomed technician performed a pm on the lift and cleared it for use at the facility. Complaint# (b)(6) was entered into our system.

Manufacturer Narrative: This report or other information submitted by joerns healthcare under 21 cfr part 803, and any release by fda of that report information, does not reflect a conclusion or admission by joerns healthcare, its employees, its contract service firms, or their employees, finished device suppliers, or their employees caused or contributed to the reportable event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7444620&pc=FSA

IX. MEDCARE MEDCARE MECHANICAL LIFT SLING

Event Date 02/23/2018
Event Type Death

Event Description Pt was being lifted from his bed to a chair via a mechanical lift at (b)(6). While the pt was suspended in the air, one of the loops on a strap of the lift sling broke and the pt fell, striking his head on the ground. He suffered a traumatic head injury and later died from his injuries. The cna performing the lift did not use the assistance of a second staff member per nursing home policy, and a different loop broke on the mechanical lift sling about a week prior, but the sling was never replaced. According to other staff members, the loops were frayed and

the seams were weak when they used it for transferring the pt. Nursing home was cited by (b)(4) for multiple violations related to this incident.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7650118&pc=FSA

X. INVACARE TAYLOR STREET POWER LIFT W/LOW BASE-PLUS 9153633519 LIFT, PATIENT, NON-AC-POWERED

Model Number NA:RPL450-1
Device Problem Detachment of device or device component
Event Date 03/05/2018
Event Type Death

Event Description: This complaint was discovered during a monthly check of the maude database, invacare has received no other information concerning this event. It is alleged two staff members were attempting to transfer a patient from a bed to a wheelchair, using an rpl450-1 power lift, the cradle became detached from the boom. The individual fell hitting their head on the base, and the cradle landed on the individual. It allegedly caused internal injuries that led to death.

Manufacturer Narrative: Based on the limited information provided, a device malfunction cannot be confirmed. The complaint could not be verified, and the underlying cause could not be determined. The rpl450-1 power lift is/has been manufactured by invamex, invacare (b)(4), and invacare rehabilitation equipment co. (suzhou); but because the serial number is not known, this medwatch is being filed under invacare (b)(4). The invacare reliant rpl450-1 user manual states, "after any adjustments, repair or service and before use, make sure all attaching hardware is tightened securely - otherwise, injury or damage may occur. " additionally, the maintenance safety inspection checklist states to inspect/adjust monthly the boom: check all hardware and hanger bar supports, and the hanger bar: check the bolt/hooks for wear or damage. Should additional information become available, a supplemental record will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7605364&pc=FSA

XI. APEX HEALTH CARE MFG., INC. HOYER ADVANCE-E PATIENT LIFT, PRODUCT CODE: FSA

Model Number HOY-ADVANCE-E
Device Problem Device handling issue
Event Date 11/28/2017
Event Type Injury

Event Description: We received this mdr from the customer (b)(4) and stating the following events at mdr# 3009402404-2017-00059 on (b)(6) 2017 and we have entered into our system as to this event. It was reported to the manufacturer by the end user, per the end user, patient's daughter called in and requested (b)(4) send a person to the parent's home to show them how to use a hoy-advance-e lift s/n (b)(4) they recently received. Daughter claimed that she and her

mother where trying to lift the patient from the bed to a chair when the lift tipped side ways and patient fell against a table cutting his left arm. Daughter claims her they had to call paramedics to get patient up and to a hospital for his wound to be taken care of. Per (b)(4) technical support, "upon further inquiry regarding the lift function indicates they did not get the legs locked in to the pedal control per instructions in the user manual page 6. This left the legs free and not locked into the pedal control. I tried to explain to them how to get them locked in but they were unable to achieve this. " complaint# (b)(4) were entered into (b)(4) system to have the lift returned to (b)(4) for investigation. As of this writing, the lift has not been returned.