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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY REPORTING

Mfr Report #
5555555-2005-55555

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (2/13)

Page 1 of ____

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event	3. Sex	4. Weight
XYZ12345 in confidence	4 Years *or* Date of Birth 01/01/2000	☐ Female ☑ Male	20 lbs *or* ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event *and/or* ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☑ Death 01/01/2004 *(mm/dd/yyyy)*
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
01/01/2005	01/01/2005

5. Describe Event or Problem

During procedure the patient seemed to be doing well. Then, things went a little down-hill

Continue on Pg 3

6. Relevant Tests/Laboratory Data, Including Dates

CT of lumbar spine

Continue on Pg 3

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Race -- Native Hawaiian/Other Pacific Islander
Other personal medical history -- patient was in good health before hospitalization

Continue on Pg 3

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates from/to *(If unknown, give duration or best estimate)*
#1 #2	#1 #2

4. Diagnosis for Use (Indication)

#1
#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction

#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Continue on Pg 3

D. SUSPECT MEDICAL DEVICE

1. Brand Name
The ONE Device

2. Common Device Name	2b. Procode
All in one pump, FRN	

3. Manufacturer Name, City and State
USA Device Manufacturer,555 Manufacturer Drive, Manufacturer Drive2, Manufacturer City, XZ 12345-1234

4. Model #	Lot #	5. Operator of Device
ABCDE	ABCD123	☐ Health Professional
Catalog #	Exp. Date *(mm/dd/yyyy)*	☐ Lay User/Patient
SMTFY999	01/01/2006	☑ Other: hosp worker
Serial #	Unique Identifier (UDI) #	
XYZ45678	1234567891011	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
01/01/2003	01/10/2003

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☑ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
American Reprocessor Choice, 41 New Street, New City, ZC 88887-7272, fax 888-888-888, email repr@noone.com

10. Device Available for Evaluation? *(Do not send to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on 01/01/2005 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
Date -- 03/03/2003

Continue on Pg 3

E. INITIAL REPORTER

1. Name and Address
Jane Adams Doe, Get Better Hospital
888 No Street1, No Street2
No City, XY 55555-5555

Phone #	Email Address
1-555-555-5555	nowhere@nowhere.com

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Audiologist	☑ Yes ☐ No ☐ Unkown

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FDA USE ONLY

MEDWATCH

FORM FDA 3500A (2/13) *(continued)* **Page 2 of ____**

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One
☑ User Facility ☐ Importer

2. UF/Importer Report Number
555555555-2005-0001

3. User Facility or Importer Name/Address
Get Better Hospital
888 No Street1
No Street2
No City, XY 55555-5555
WORLD email -- noone@noone.com

4. Contact Person
Adam M. John III

5. Phone Number
555-555-5555

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
01/01/2005

7. Type of Report
☑ Initial
☐ Follow-up #____

8. Date of this Report *(mm/dd/yyyy)*

9. Approximate Age of Device
4 YR

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ — ____ — ____
Device Code ____ — ____ — ____

11. Report Sent to FDA?
☑ Yes 01/01/2005
☐ No *(mm/dd/yyyy)*

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatience Treatment Facility
☑ Other On the road

13. Report Sent to Manufacturer?
☑ Yes 01/10/2005
☐ No *(mm/dd/yyyy)*

14. Manufacturer Name/Address
American Reprocessor Choice,
41 New Street,
New City, ZC 88887-7272,
fax 888-888-888, email repr@noone.com

G. ALL MANUFACTURERS

1. Contact Office — Name/Address *(and Manufacturing Site for Devices)*
Mr. John Quincy Adams
USA Device Manufacturer - MDR Contact
999 Lala Lane
Lala Lane Line2
Bam Bam, ZB 12345-8888
USA, FAX - 777-777-7777
phone - 111-666-7777
email - mdrContact@noone.com

2. Phone Number

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company
☐ Representatives
☐ Distributor
☑ Other: source not known

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/14/2005

5. (A)NDA # ____
IND # ____
BLA # ____
PMA/510(k) # P000001

6. If IND, Give Protocol #

7. Type of Report
☐ 5-Day ☐ 30-Day
☐ 7-Day ☐ Periodic
☐ 10-Day ☐ Initial
☐ 15-Day ☑ Follow-Up# 8

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

8. Adverse Event Term(s)

9. Manufacturer Report #
5555555-2005-55555

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☑ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-Up, What Type?
☐ Correction
☑ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☑ No *(Attach page to explain why not)* or provide code:
81

4. Device Manufacture Date *(mm/dd/yyyy)*
01/2005

5. Labeled for Single Use?
☑ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)

Patient Code	1708	2229		
Device Code	1450	1450		
Method	12			
Results	704			
Conclusions	41			

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☑ Other: something else happened

8. Usage of Device
☑ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
7778877

10. ☑ Additional Manufacturer Narrative *and/or* 11. ☐ Corrected Data
Our evaluation revealed that at this moment we need to evaluate more; Attached is some more information.

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B.5. Describe Event or Problem *(continued)*

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B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Back to Item B.6

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Back to Item C.10 | Back to Item D.11

Other Remarks