

MEDWATCH
FDA eSubmitter Generated Form 3500A

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

Mfr Report #:	1234567-2023-00001
UF/Importer Report #:	
Form Code:	
Exemption Number:	ABC1234567

A. PATIENT INFORMATION

1. Patient Identifier (In confidence) JD	2. Age at Time of Event, Date of Birth 50 Year(s), 01-May-1973	3a. Sex Male	3b. Gender Other: Other g...	4. Weight 180 Pound(s)
5. Ethnicity () Hispanic/Latino (•) Not Hispanic/Latino				
6. Race [x] Asian [x] White [] American Indian or Alaskan Native [] Native Hawaiian or Other Pacific Islander [] Black or African American				

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [x] Product Problem (e.g., defects/malfunctions)	
2. Outcomes Attributed to Adverse Event (Checked all that apply) [x] Death: 02-Jul-2023 (dd-mmm-yyyy) [] Disability or Permanent Damage [] Life-threatening [] Congenital Anomaly/Birth Defect [] Hospitalization (initial or prolonged) [x] Other Serious or Important Medical Events [] Required Intervention to Prevent Permanent Impairment/Damage	
3. Date of Event (dd-mmm-yyyy) 01-Jul-2023	4. Date of this Report (dd-mmm-yyyy) 01-Aug-2023
5. Describe Event or Problem Sample event narrative.	
6. Relevant Tests/Laboratory Data, Including Dates Sample lab test narrative.	
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Sample medical history narrative.	

C. SUSPECT PRODUCT(S)

D. SUSPECT MEDICAL DEVICE

1. Brand Name BYPASS BRAND	2. Common Device Name VENTRICULAR (ASSIST) BYPASS, Product Code: DSQ	
3. Manufacturer Name, City and State BYPASS Mfr D3 1000 N Glebe Rd Unit 101 Arlington, VA 22203-3760, USA Fax:(703) 925-3201 Email:support@bypassmfr.com	4. Model # M2000	Catalog # C4512
	Serial # S100012345	Lot # L000001234
	Expiration Date (dd-mmm-yyyy) 01-Jan-2025	
	Unique Identifier (UDI) # (01)5102222233336(11)141231(17)150707(10)A213B1(21)1234	
5. Operator of Device Other: Technician	6a. If Implanted, Give Date (dd-mmm-yyyy) 30-Jun-2023	6b. If Explanted, Give Date (dd-mmm-yyyy) 01-Jul-2023
7a. Is this a Single-Use Device that was reprocessed and Reused on a Patient? (•) Yes () No	7b. If yes, Enter Name and Address of Reprocessor Reprocessor Name IGNACIO ZARAGOZA NO. 10 MARIA ISABEL CHIHUAHUA, CIUDAD JUAREZ 32560, MEX Fax:333-615-8540 Email:support@reprocessor.com	
8. Was this device serviced by a third party? (•) Yes () No () Unknown	9. Device Available for Evaluation? (Do not send to FDA) () Yes (•) No [x] Returned to Manufacturer: 02-Jul-2023 (dd-mmm-yyyy)	

10. ConComitant Medical Products and Therapy Dates (Excludes treatment of event)

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Concomitant Product 1	01-Jan-2022 (dd-mmm-yyyy)
Concomitant Product 2	01-Feb-2022 (dd-mmm-yyyy)

E. INITIAL REPORTER

1. Name and Address Mr. John Alan Doe John's Hospital 1900 Orleans St Unit 901 Baltimore, MD 21287-0400, USA Telephone:(410) 737-9001 Ext: 12345 Fax:(410) 737-9002 Email:jad@gmail.com	2. Health Professional? (.) Yes () No
	3. Occupation Physician
	4. Initial Reporter Also Sent Report to FDA? (.) Yes () No () Unk

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

1. User Facility or Importer () User Facility () Importer	2. User Facility/Importer Report Number
3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number	6. Date UF/Importer Became Aware of Event (dd-mmm-yyyy)
	7. Type of Report () Initial () Follow-up
	8. Date of This Report (dd-mmm-yyyy)
10. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code:	14. Manufacturer Name/Address
11. Report Sent to FDA? () Yes () No	
12. Location Where Event Occurred	
13. Report Sent to Manufacturer? () Yes () No	

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility Ms. Pam Annette Reese Bypass Mfr G1 Contact 3000 Glebe Rd Unit 8000 Arlington, VA 22203-3760, USA Telephone:(703) 925-8821 Ext: 12345 Fax:(703) 925-3761 Email:pam.a.reese@bypassmfr.com	1. Contact Office - Manufacturing Site BYPASS Mfr G1 Site 1000 N Glebe Rd Unit 101 Arlington, VA 22203-3760, USA Fax:(703) 925-3201 Email:support@bypassmfr.com	
2. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> Study <input checked="" type="checkbox"/> User Facility <input type="checkbox"/> Literature <input type="checkbox"/> Company Representative <input type="checkbox"/> Consumer <input type="checkbox"/> Distributor/Importer <input checked="" type="checkbox"/> Other: Other source description	3. Date Received by Manufacturer (dd-mmm-yyyy) 02-Jul-2023	
	4. Premarket Identification <input type="checkbox"/> Combination Product	PMA/510(k): P012345 Device BLA: BLA12345
	6. Type of Report <input type="checkbox"/> 5-day <input type="checkbox"/> Periodic <input type="checkbox"/> 7-day <input checked="" type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up	5. If IND/PreANDA, Give Protocol #
	7. Adverse Event Term(s) Term1;Term2;Term3	8. Manufacturer Report Number 1234567-2023-00001

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<input checked="" type="checkbox"/> 30-day			
H. DEVICE MANUFACTURERS ONLY			
1. Type of Reportable Event (•) Death () Serious Injury () Malfunction <input type="checkbox"/> Summary Report No. of Events Summarized:	2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation	3. Device Evaluated by Manufacturer? () Yes (•) No	
4. Device Manufacture Date (dd-mmm-yyyy) 01-Dec-2022		6. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: 1884 - 1708 Health Effect - Impact Code: 1802 - 4634 Medical Device Problem Code: 2896 - 1384 Component Code: 765 - 527 Type of Investigation: 10 - 4110 Investigation Findings: 202 - 110 Investigation Conclusions: 4318 - 4302	
5. Labeled for Single Use? () Yes (•) No			
7. If Remedial Action initiated, Check Type <input checked="" type="checkbox"/> Recall <input checked="" type="checkbox"/> Repair <input type="checkbox"/> Replace <input type="checkbox"/> Relabeling <input checked="" type="checkbox"/> Other: Other remedial action description		8. Usage of Device (•) Initial Use of Device () Reuse () Unknown	9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number RN12345 10. Related Report Numbers: 1234567890-2023-00001, MW12345678
11. Additional Manufacturer Narrative Sample additional manufacturer narrative.			
File Attachments			
Sample PDF (sample_attachment.pdf)			