

MEDWATCH
FDA eSubmitter Generated Form 3500A

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

Mfr Report #:
UF/Importer Report #: 1234567890-2023-0001
Form Code:
Exemption Number:

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)510222233336(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 1234567890-2023-0001
3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number Mr. Tom Robin Brooks John's Healthcare System 1901 Orleans St, Unit 501 Baltimore, MD 21287-0400, USA Telephone:(410) 737-2001 Ext: 12345 Fax:(410) 737-2001 Email:trbrooks@johnshospital.com	6. Date UF/Importer Became Aware of Event (dd-mmm-yyyy) 02-Jul-2023
	7. Type of Report (.) Initial () Follow-up
	8. Date of This Report (dd-mmm-yyyy) 01-Aug-2023
	9. Approximate Age of Device 2 Year(s)
10. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: 1708 - 1884 Health Effect - Impact Code: 1802 - 4634 Medical Device Problem Code: 2896 - 1384 Component Code: 765 - 527	14. Manufacturer Name/Address BYPASS Mfr 1000 N Glebe Rd Unit 101 Arlington, VA 22203-3760, USA Fax:(703) 925-3201 Email:support@bypassmfr.com
11. Report Sent to FDA? (.) Yes: 01-Aug-2023 (dd-mmm-yyyy) () No	
12. Location Where Event Occurred Other: Other location description	
13. Report Sent to Manufacturer? (.) Yes: 08/01/2023 (dd-mmm-yyyy) () No	

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility	1. Contact Office - Manufacturing Site
2. Report Source (Check all that apply) [] Foreign [] Health Professional [] Study [] User Facility [] Literature [] Company Representative [] Consumer [] Distributor/Importer [] Other	3. Date Received by Manufacturer (dd-mmm-yyyy)
	4. Premarket Identification PMA/510(k): [] Combination Product Device BLA:
	5. If IND/PreANDA, Give Protocol #
6. Type of Report [] 5-day [] Periodic [] 7-day [] Initial [] 15-day [] Follow-up [] 30-day	7. Adverse Event Term(s)
	8. Manufacturer Report Number

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	3. Device Evaluated by Manufacturer? () Yes () No
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<input type="checkbox"/> Summary Report No. of Events Summarized:		<input type="checkbox"/> Device Evaluation			
4. Device Manufacture Date (dd-mmm-yyyy)			6. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code: Type of Investigation: Investigation Findings: Investigation Conclusions:		
5. Labeled for Single Use? () Yes () No					
7. If Remedial Action initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Notification <input type="checkbox"/> Repair <input type="checkbox"/> Inspection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Relabeling <input type="checkbox"/> Modification/Adjustment <input type="checkbox"/> Other			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 10. Related Report Numbers:
11. Additional Manufacturer Narrative					
File Attachments					
Sample PDF (sample_attachment.pdf)					