

MEDWATCH
FDA eSubmitter Generated Form 3500A

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

Mfr Report #:	1234567-2023-00002
UF/Importer Report #:	
Form Code:	
Exemption Number:	ABC1234567

A. PATIENT INFORMATION				
1. Patient Identifier (In confidence)	2. Age at Time of Event, Date of Birth	3a. Sex	3b. Gender	4. Weight
5. Ethnicity () Hispanic/Latino () Not Hispanic/Latino				
6. Race [] Asian [] White [] American Indian or Alaskan Native [] Native Hawaiian or Other Pacific Islander [] Black or African American				
B. ADVERSE EVENT OR PRODUCT PROBLEM				
1. [] Adverse Event and/or [x] Product Problem (e.g., defects/malfunctions)				
2. Outcomes Attributed to Adverse Event (Checked all that apply) [] Death [] Disability or Permanent Damage [] Life-threatening [] Congenital Anomaly/Birth Defect [] Hospitalization (initial or prolonged) [] 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 summary event narrative.				
6. Relevant Tests/Laboratory Data, Including Dates				
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)				
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 # M12345	Catalog # C12345	
		Serial #	Lot # L12345	
		Expiration Date (dd-mmm-yyyy)		
		Unique Identifier (UDI) # (01)5102222233336, (01)5102222233337, (01)5102222233338		
5. Operator of Device		6a. If Implanted, Give Date (dd-mmm-yyyy)		6b. If Explanted, Give Date (dd-mmm-yyyy)
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 [] Returned to Manufacturer		
10. ConComitant Medical Products and Therapy Dates (Excludes treatment of event)				

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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)	9. Approximate Age of Device
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) [] Foreign [x] Health Professional [] Study [x] User Facility [] Literature [] Company Representative [] Consumer [] Distributor/Importer [x] Other: Other source description	3. Date Received by Manufacturer (dd-mmm-yyyy) 02-Jul-2023	
	4. Premarket Identification PMA/510(k): P012345 [] Combination Product Device BLA: BLA12345	
	5. If IND/PreANDA, Give Protocol #	
6. Type of Report [] 5-day [] Periodic [] 7-day [x] Initial [] 15-day [] Follow-up [x] 30-day	7. Adverse Event Term(s) Term1;Term2;Term3	8. Manufacturer Report Number 1234567-2023-00002
H. DEVICE MANUFACTURERS ONLY		

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1. Type of Reportable Event <input type="radio"/> Death <input type="radio"/> Serious Injury <input checked="" type="radio"/> Malfunction <input checked="" type="checkbox"/> Summary Report No. of Events Summarized: 1000	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? <input type="radio"/> Yes <input checked="" type="radio"/> No	
4. Device Manufacture Date (dd-mmm-yyyy)		6. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: 4582 Health Effect - Impact Code: 2199 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? <input type="radio"/> Yes <input checked="" type="radio"/> No			
7. If Remedial Action initiated, Check Type <input checked="" type="checkbox"/> Recall <input type="checkbox"/> Notification <input checked="" 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 checked="" type="checkbox"/> Other: Other remedial action description		8. Usage of Device <input checked="" type="radio"/> Initial Use of Device <input type="radio"/> Reuse <input type="radio"/> Unknown	9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number RN12345 10. Related Report Numbers:
11. Additional Manufacturer Narrative Sample summary manufacturer narrative.			
File Attachments			
Sample PDF (sample_attachment.pdf)			