

MEDWATCH  
FDA eSubmitter Generated Form 3500A

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

Mfr Report #:	
UF/Importer Report #:	1234567890-2023-09001
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)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**

<b>1. Name and Address</b> 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	<b>2. Health Professional?</b> (.) Yes ( ) No
	<b>3. Occupation</b> Physician
	<b>4. Initial Reporter Also Sent Report to FDA?</b> (.) Yes ( ) No ( ) Unk

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

<b>1. User Facility or Importer</b> ( ) User Facility (.) Importer	<b>2. User Facility/Importer Report Number</b> 1234567890-2023-09001
<b>3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number</b> Mrs. Jane April Flowers Device Importer 400 Peace Ave, Unit 501 Buffalo, NY 14201-0001, USA Telephone:(716) 343-6001 Ext: 12345 Fax:(716) 343-6002 Email:jaflores@importer.com	<b>6. Date UF/Importer Became Aware of Event (dd-mmm-yyyy)</b> 02-Jul-2023
	<b>7. Type of Report</b> (.) Initial ( ) Follow-up
	<b>8. Date of This Report (dd-mmm-yyyy)</b> 01-Aug-2023
	<b>9. Approximate Age of Device</b> 2 Year(s)
<b>10. Adverse Event Problem (Refer to coding manual)</b> Health Effect - Clinical Code: 1708 - 1884 Health Effect - Impact Code: 1802 - 4634 Medical Device Problem Code: 2896 - 1384 Component Code: 765 - 527	<b>14. Manufacturer Name/Address</b> BYPASS Mfr 1000 N Glebe Rd Unit 101 Arlington, VA 22203-3760, USA Fax:(703) 925-3201 Email:support@bypassmfr.com
<b>11. Report Sent to FDA?</b> (.) Yes: 01-Aug-2023 (dd-mmm-yyyy) ( ) No	
<b>12. Location Where Event Occurred</b> Other: Other location description	
<b>13. Report Sent to Manufacturer?</b> (.) Yes: 08/01/2023 (dd-mmm-yyyy) ( ) No	

**G. ALL MANUFACTURERS**

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

**H. DEVICE MANUFACTURERS ONLY**

<b>1. Type of Reportable Event</b> ( ) Death ( ) Serious Injury ( ) Malfunction	<b>2. If Follow-up, What Type?</b> [ ] Correction [ ] Additional Information [ ] Response to FDA Request	<b>3. Device Evaluated by Manufacturer?</b> ( ) 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)					