

Mfr Report #:	1234567-2023-00003
UF/Importer Report #:	
Form Code:	
Exemption Number:	

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 <div> <input checked="" type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American </div> <div> <input checked="" type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander </div>				

1. [<input checked="" type="checkbox"/>] Adverse Event and/or [<input type="checkbox"/>] Product Problem (e.g., defects/malfunctions)	
2. Outcomes Attributed to Adverse Event (Checked all that apply) <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input checked="" type="checkbox"/> Hospitalization (initial or prolonged) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage </div> <div> <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Other Serious or Important Medical Events </div> </div>	
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 tests 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.	

Drug Product # 1				
Drug Type: NDA		Approval #: NDA12345		If IND/Pre-ANDA, Give Protocol #:
1a. Name and Strength: Drug1 500mg			1c. NDC # or Unique ID: NDC12345	
1b. Manufacturer/Compounder: Drug1 Mfr			1d. Lot #: L10001	
2a. List Medical Product and Treatment Given at the Same Time Of the Event and Date See Section D10 for all Concomitant Medical Product and Therapy Date information				
3a. Dose: 500	3b. Dose Unit: 003	3c. Number of separate dosages: 2	3d. Frequency: 2	3e. Frequency Unit: 804
3f. Route Used: 048			4. Treatment Dates/Therapy Dates: 01-Jun-2023 to 01-Jul-2023	
5. Diagnosis for Use (Indication): Indication here			6. Product Type: <input checked="" type="checkbox"/> OTC <input checked="" type="checkbox"/> Generic <input type="checkbox"/> Compounded <input type="checkbox"/> Biosimilar <input type="checkbox"/> Pre-ANDA <input type="checkbox"/> Pre-1938	
			7. Expiration Date 01-Jan-2026	
			8. Event Abated After Use Stopped or Dose Reduced? (•) Yes () No () Doesn't Apply	
			9. Event Reappeared After Reintroduction? () Yes (•) No () Doesn't Apply	

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Drug Product # 2				
Drug Type: IND		Approval #: IND12345		If IND/Pre-ANDA, Give Protocol #: P123
1a. Name and Strength: Drug2 50mg			1c. NDC # or Unique ID: UID12345	
1b. Manufacturer/Compounder: Drug2 Mfr			1d. Lot #: L20001	
2a. List Medical Product and Treatment Given at the Same Time Of the Event and Date See Section D10 for all Concomitant Medical Product and Therapy Date information				
3a. Dose: 50	3b. Dose Unit: 003	3c. Number of separate dosages: 1	3d. Frequency: 1	3e. Frequency Unit: 804
3f. Route Used: 061			4. Treatment Dates/Therapy Dates: 01-May-2023 to 01-Jul-2023	
5. Diagnosis for Use (Indication): Diagnosis for use			6. Product Type: <input type="checkbox"/> OTC <input type="checkbox"/> Generic <input checked="" type="checkbox"/> Compounded <input checked="" type="checkbox"/> Biosimilar <input type="checkbox"/> Pre-ANDA <input type="checkbox"/> Pre-1938	
			7. Expiration Date 01-Sep-2023	
			8. Event Abated After Use Stopped or Dose Reduced? () Yes () No (•) Doesn't Apply	
			9. Event Reappeared After Reintroduction? () Yes () No (•) Doesn't Apply	

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 # S1234567	Lot # L12345
		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 <input type="checkbox"/> Returned to Manufacturer	

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

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Concomitant Product 1 Concomitant Product 2		01-Jan-2022 (dd-mmm-yyyy) 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)	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 [x] 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		7. Adverse Event Term(s) Term1;Term2;Term3	8. Manufacturer Report Number 1234567-2023-00003

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<input checked="" type="checkbox"/> 30-day			
H. DEVICE MANUFACTURERS ONLY			
1. Type of Reportable Event <input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
4. Device Manufacture Date (dd-mmm-yyyy) 01-Dec-2022		6. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: 1888 Health Effect - Impact Code: 4607 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="checkbox"/> Yes <input checked="" type="checkbox"/> 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="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> 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 manufacturer narrative.			
File Attachments			
Sample PDF (sample_attachment.pdf)			