



**CONFIDENTIAL
VARIANCE REPORT**

For use by user-facilities,
distributions and manufactures for
MANDATORY reporting

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Mfr. Report #
UF/Dlst report #
FDA use only

A. Patient Information			
1. Patient Identifier In confidence	2. Age at time of event: or _____ Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
B. Adverse event or product problem			
1. Adverse event and/or Product problem (e.g. defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death _____ (mo/day/yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization-initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____			
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)		
5. Describe event or problem			
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 medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 _____			
#2 _____			
2. Dose, frequency & route used		3. Therapy dates (if known, give duration from/to (or best estimate))	
#1 _____		#1 _____	
#2 _____		#2 _____	
4. Diagnosis for use (indication)			5. Event abated after use stopped or dose reduced
#1 _____			
#2 _____			#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> NA
6. Lot # (if known)		7. Exp. date (if known)	
#1 _____		#1 _____	
#2 _____		#2 _____	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> NA			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> NA			
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
D. Suspect Medical Device			
1. Brand name			
2. Type of device			
3. Manufacturer name and address			4. Operator of device
			<input type="checkbox"/> health professional
			<input type="checkbox"/> lay user/patient
			<input type="checkbox"/> other:
6. model # _____			5. Expiration date
catalog # _____			7. If implanted, give date
serial # _____			8. If explanted, give date
lot # _____			
other # _____			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
E. Initial Reporter			
1. Name, address & phone #			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no			
3. Occupation		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	
Submission of report does not constitute an admission that medical personnel, user facility, distributor, manufacturer of product caused or contributed to the event.			