REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبنان وزارة الصحة العامة المدير العام

رقم المحفوظات: ٥> ك ٧ بح رقسم اللصادر : ٢، ٧/ ٢/ ١/٢٨٧ بيسروت، في : ٢- ايمر ١٣- ١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس Prostheses, Gastroesophageal, Antireflux, EsophyX2

الجهاز المعني بالمتابعة:

- Prostheses, Gastroesophageal, Antireflux, EsophyX2
- Trade Mark: Endogastric Solutions Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA ،

الذي يشير الى وجود خلل في عمل الجهاز المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن وكالة ال FDA
 - :2
 - م دائرة البرامج والمشاريع
 - المستشفيات الحكومية
 - · المحفوظات



Medical & Radiation Emitting Device Recalls

510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴ CFR Title 21¹⁵|Radiation-Emitting Products¹⁶|X-Ray Assembler¹⁷|Medsun Reports¹⁸|CLIA¹⁹|TPLC²⁰

End Dev August 17, 2013 Z-1982-2013 EndoGastric Solut Models R2001 an gastroesophageal UN-EXPIRED dev and following LOT 401219, 401220, 4 401256, 401259, 4 dates (1/31/2013, following LOT nun 400963, 400973, 4 400990, 401004, -	rice + tions Eso d R2002. I reflux dis vices with r numbers 401225, 4 401267, 4 2/28/201 nbers: 40 400976, 4	pphyX2 I . Indicat isease. n Expirat rs: 401127 401227 401227 13, 3/31	2 Device ated for th 132, 401 7, 40123 9, 40127 1/2013 4	he treatme es (8/31/2 147, 4011 0, 401233 1, 401274	osa Faste ent of sy 2013, 11. 152, 401 3, 40123 4, and 40	/mptomati /30/2013, 156, 4012 66, 401246 01276. EX	12/31/20 159, 40116 5, 401248,	13, an 57, 40 4012	
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