

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FDA Use Only



3005185555



898820

**ANNUAL REGISTRATION OF
DEVICE ESTABLISHMENT**

REGISTRATION NUMBER

3005185555 for 2007

OWNER/OPERATOR NUMBER

9075625

1. REGISTERED ESTABLISHMENT INFORMATION (Enter corrections below on right side)

Select Only One: Information is Correct, No Changes No Longer a Device Establishment Out of Business Establishment Name/Address Change (Moved to new location) Establishment Name/Address Change (Merged with other establishment)

TMX ENGINEERING & MANUFACTURING, INC.

2141 S. STANDARD AVE.

SANTA ANA, CA 92707

Establishment Name

Address

Address

City, State, ZIP Code

Foreign State or Province/Country/Postal Code

2. ESTABLISHMENT TYPES (For each type check one box)

- 1. Contract Manufacturer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 2. Contract Sterilizer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 3. Foreign Exporter Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 4. Initial Distributor/Importer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 5. Manufacturer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 6. Remanufacturer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 7. Repackager/Relabeler Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 8. Reprocessor of Single Use Devices Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 9. Specification Developer Current Est. Type Correct Delete this Establishment Type Add this Establishment Type
- 10. U.S. Manufacturer of Export Only Devices Current Est. Type Correct Delete this Establishment Type Add this Establishment Type

3. OWNER/OPERATOR (O/O) INFORMATION (Enter corrections below on right side)

Select Only One: Information is Correct, No Changes O/O Name/Address Change, Same Company With New Name or Address O/O Change, Sold Establishment

TMX ENGINEERING & MANUFACTURING, INC.

2141 S. STANDARD AVE.

SANTA ANA, CA 92707

Business Name

Address

Address

City, State, ZIP Code

Foreign State or Province/Country/Postal Code

Phone Number (incl. area codes; if foreign, incl. country & local codes)


PH: (714) 641-5884 x12

O/O Number (if changed)

O/O Number 9075625

4. OTHER BUSINESS TRADING NAMES (For each name listed check one box; add new names if any)

- a. Correct No Longer Used Corrected Name
- b. Correct No Longer Used Corrected Name
- c. Correct No Longer Used Corrected Name

NEW TRADING NAME	NEW TRADING NAME	REGISTRATION NUMBER	3005185555 for 2007
5. OFFICIAL CORRESPONDENT INFORMATION <i>(Enter corrections below on right side)</i> Select Only One: <input checked="" type="checkbox"/> Information is Correct, No Changes <input type="checkbox"/> Correction Needed			
MR. GUS TOUBIA TMX ENGINEERING & MANUFACTURING, INC. 2141 S. STANDARD AVE. SANTA ANA, CA 92707 gus@tmxengineering.com PH: (714) 641-5884 x12 FAX: (714) 557-5361		Name of Individual Business Name Address Address City, State, ZIP Code (If foreign, enter: City, State or Province, Country, and Postal Code) Email Address Phone Number (incl. area code; if foreign, incl. country & local codes) FAX Number (incl. area code; if foreign, incl. country & local codes)	
6. US AGENT INFORMATION (Foreign Establishments Only) <i>(Enter corrections below on right side)</i> Select Only One: <input type="checkbox"/> Information is Correct, No Changes <input type="checkbox"/> Correction Needed			
SIGNATURE OF OFFICIAL CORRESPONDENT 		NAME GUS TOUBIA THE RESIDENT DATE SIGNED 1-18-07	
<small>NOTE: This form is authorized by Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2) (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.</small>			
Instructions 1. Review data on left: hand side of form 2. If information is correct select the box "Information is Correct, No Changes" for items 1, 3, 5, and 6. An answer must be selected regardless of any changes. For items 2 and 4 you will need to check a box for each Establishment Type or Business Name. 3. If changes are needed select the box that indicates the reason for the change and make the corrections on the right hand side of the form. 4. Review the attached listing information and if changes are needed fill out Form FDA 2892. To obtain a Form FDA 2892 go to: http://www.fda.gov/cdrh/reglistpage.html 5. Sign the form and mail to: Food and Drug Administration Center for Devices and Radiological Health, HFZ-308 9200 Corporate Blvd. Rockville, MD 20850-4015		Some definitions to assist you in determining why changes are being made: 1. No Longer a Device Establishment - The establishment is no longer engaged in activities which require it to be registered as a medical device establishment, but the establishment is still in existence for other activities or purposes. 2. Out of Business - The establishment has ceased to exist as an identifiable organization. 3. Owner/Operator Change - Sold Establishment - Indicates Owner/Operator has changed because establishment sold to another firm. 4. Owner/Operator Name/Address Change - Same Company with New Name or Address - Indicates only a new name and address for Owner/Operator, but remains under same ownership. 5. Establishment Type - definitions can be found at: http://www.fda.gov/cdrh/reglistpage.html	
6. If no changes were needed then mark "No Changes" on the lower left hand corner of your envelope.			

Device Listing Report

Please DO NOT return this device listing report to FDA. Changes to listing information must be made using form FDA 2892, Device Listing.

3005185555

TMX ENGINEERING & MANUFACTURING, INC.

Class:	1	Product Code	GDF	Classification Name:	GUIDE, NEEDLE, SURGICAL
Date of Last Update	10-Aug-2005	Listing #	E237199	Proprietary Name:	4CLOSURE
Establishment Type(s):	MANUFACTURER				
				Common Name:	STERILE FASCIA CLOSURE KIT WITH SUTURE PASSER INSTRUMENT AND NEEDLE GUIDE

Total Active Listings: 1