Date: October 19, 2016

Establishment:
4 MED LTD.
7 shikma st sapirim i.z
p.b. box 1028
sderot hadarom, ISRAEL 8700101
Registration Number: 3004135030
FEI Number*: 3004135030
Status: Active
Date of Registration Status: 2016

Owner/Operator:
4 MED LTD.6
16 shivat zion street
kfar sava, ISRAEL 44286
Owner/Operator Number: 90583037

Official Correspondent:
samuel bar-ziv
4 MED LTD.
16 shivat zion
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Phone: 972-9-7425984

US Agent:
MICHELLEELI
MRS. MICHELLE ELI
1621 hoover avenue
south bend , IN 46615
Phone: 574 234
Fax: 574 237
Email: michelle.eli@sbcglobal.net

Proprietary Name:	"Rosenberg" Skin Graft Mesher; "Rosenberg" Variable Mesher
Classification Name:	EXPANDER, SURGICAL, SKIN GRAFT
Product Code:	FZW
Device Class:	1
Regulation Number:	878.4800
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	4 MED LTD.
Registered Establishment Number:	3004135030
Owner/Operator:	4 MED LTD.
Owner/Operator Number:	9058303
Establishment Operations:	Manufacturer

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Product Classification

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Device	Expander, Surgical, Skin Graft
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	FZW
Premarket Review	Office of Device Evaluation[6](ODE) Division of Surgical Devices (DSD) General Surgery Devices Branch One - Light Based/Laser (GSDB1)
Submission Type	510(K) Exempt
Regulation Number	878.4800[7]
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices[9]) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892[10]. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892[11], a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website[12] for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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11. /scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpartfrom=862&cfrpartto=892
12. http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/default.htm

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U.S. Food and Drug Administration
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Silver Spring, MD 20993
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FDA

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2016.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

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See Related Information[9]

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2016]
[CITE: 21CFR878.4800]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES

Subpart E--Surgical Devices

Sec. 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 878.9.

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