DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2015

Theo Manufacturing BV
Mrs. Monique Gottgens
Quality Assurance/Regulatory Affairs Manager
Capucijnenstraat 71
Maastricht 6211 RP
The Netherlands

Re: K150676
Trade/Device Name: L-Mesitran® Soft and L-Mesitran® Tulle
(L-Mesitran Dressing Family II)
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 20, 2015
Received: December 2, 2015

Dear Mrs. Gottgens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150676

Device Name
L-Mesitran® Soft and L-Mesitran® Tulle (L-Mesitran Dressing Family II)

Indications for Use *(Describe)*

a) Over-The-Counter (OTC) use

The L-Mesitran Dressing Family II – Soft and Tulle provide a moist environment conducive to wound healing and are indicated for light to moderately exuding wounds. For over the counter use, L-Mesitran Dressing Family II may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

b) Prescription (Rx) use

Under the supervision of a healthcare professional, The L-Mesitran Dressing Family II – Soft and Tulle provide a moist environment conducive to wound healing and are indicated for light to moderately exuding wounds. The L-Mesitran Dressing Family II is intended for the management of the following:

- Diabetic foot ulcers
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- Pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- Donor sites, and traumatic and surgical wounds

L-Mesitran Soft and Tulle are to be used in conjunction with other secondary dressings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510K SUMMARY

The assigned 510(k) number is:	K150676
1. Sponsor	
Company:	Theo Manufacturing BV Capucijnenstraat 71 Maastricht NL-6211 RP The Netherlands Telephone: +31 43 325 1773
Date Prepared:	December 23rd, 2015
2. Device Name	
Proprietary Names:	L-Mesitran® Dressing Family II • L-Mesitran® Soft • L-Mesitran® Tulle
Common/Usual Name:	Wound Dressing
Classification:	Unclassified
Classification Code:	Dressing, Product Code FRO
Panel:	General & Plastic Surgery
3. Predicate Devices	
	#K053613 L-Mesitran® Dressing Family I : L-Mesitran® Hydro, Border, Active and Net
	#K101793 Derma Sciences Medihoney Gel Dressings with Active Manuka Honey
4. Device Description	
L-Mesitran® Soft and Tulle are wound dressings for the use on wounds • L-Mesitran® Soft is a gel that contains: 40% medical grade honey, medical grade hypoallergenic lanolin, propylene glycol, PEG 4000, and vitamins C and E. • L-Mesitran® Tulle is a non-adherent polyethylene dressing impregnated with the patented L-Mesitran® Soft gel.	

5. Intended use

Indications for Use:

Over-The-Counter (OTC) Use
The L-Mesitran Dressing Family II – Soft and Tulle provide a moist environment conducive to wound healing and are indicated for light to moderately exuding wounds. For over the counter use, L-Mesitran Dressing Family II may be used for:
- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

L-Mesitran Soft is to be used in conjunction with other secondary dressings.

Prescription (Rx) Use
Under the supervision of a healthcare professional, L-Mesitran Soft provides a moist environment conducive to wound healing and is indicated for light to moderately exuding wounds. L-Mesitran Soft is intended for the management of the following:
- Diabetic foot ulcers
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- Pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- Donor sites, and traumatic and surgical wounds.

L-Mesitran Soft is to be used in conjunction with other secondary dressings.

6. Summary of technological characteristics compared to the predicate devices.

The technological characteristics of the L-Mesitran® Dressing Family II with honey, the L-Mesitran® Dressing Family I (Hydro/Border/Active/Net) subject of K053613 and the Medihoney Gel Dressing with Active Manuka Honey subject of K101793, are substantially equivalent in that they are honey containing wound dressings that can be covered with most commonly used secondary dressings. Also, they share same

properties in that they are intended for use as primary wound dressings and prevent the secondary dressing from adhering to the wound bed.

There are no new concerns of safety and effectiveness, therefore, the subject device is substantially equivalent to the predicate devices in this regard.

The difference in honey percentage provides the user with a wider variety of honey dressings and does not represent a significant change in technological characteristics.

The intended use of the L-Mesitran® Dressing Family II and the predicate devices are identical with respect to their intention to provide a moist environment conducive to wound healing.

In addition, both the proposed and predicate devices are intended for both OTC and prescription use.

The L-Mesitran® Dressing Family II and the predicate devices are identical with respect to their indication for management of wounds including partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

The differences in technological characteristics between the predicate devices and L-Mesitran® Dressing Family II are the different auxiliary substances used.

7. Non-clinical performance testing/data

Biocompatibility testing performed demonstrates that the L-Mesitran® Dressing Family II is safe for its intended use. The biocompatibility and performance testing included:

Cytotoxicity: Quantitative MEM-Elution Test – ISO 10993-5, 2009: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.
irritation: Intracutaneous Injection Test – ISO 10993-10, 2002, Biological evaluation of medical devices – Part 10: Tests for irritation and Delayed-Type Hypersensitivity, as amended 2006.
Sensitization: Guinea Pig Maximization Sensitization Test – ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

Preservative Efficacy Test – modified Ph.Eur. 5.1.3, harmonized with USP 51, modifications: starting inoculum at least 6 logs, reduction in bioburden at least 4 logs, microorganisms: 3 gram positive bacteria, 3 gram negative bacteria, a yeast and a mold, on aged products.

Bioburden tests – Ph.Eur. 2.6.12: 2.6.13, harmonized with USP 61;62.

8. Clinical performance testing

Not applicable.

9. Conclusions

Based on the information provided in this 510(k), Theo Manufacturing BV believes that the proposed L-Mesitran® Dressing Family II (Soft/Tulle) is substantially equivalent in function and intended use to L-Mesitran® Dressing Family I (K053613), the Medihoney Gel Dressing with Active Manuka Honey (K101793). The proposed devices raise no new issues of safety and effectiveness. The non-clinical testing performed demonstrates that the proposed device met all test specifications and is suitable and safe for its intended use.