4. 510(k) Summary

4.1.1 Sponsor:

Beau Rx Solutions, LLC
1440 South Ocean Blvd #5C
Lauderdale by the Sea, Fl 33062

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4.1.2 Contact:

Thomas L McGraw, President
Phone: 1-954-817-6155
Fax 1-954-782-0018
E-mail Silospheres@bellsouth net
Date of Preparation October 15, 2008

4.1.3 Contract Manufacturer:

A I G Technologies, Incorporated
1917 N W 40th Court
Pompano Beach, Florida 33064
Reg #3003511617
Label Code 66756

4.1.4 Device Identification:

Proprietary Name Beau Rx™ Scar Care Gel
Common Name Silicone Scar Gel
Classification Name: Elastomer, Silicone, for Scar Management
CFR 878 4025
Product Code MDA

4.1.5 Substantial Equivalence:

Beau Rx Solutions product, Beau Rx™ Scar Care Gel, is substantially equivalent in design, composition and function compared to Kelo-cote® Scar Gel manufactured by Advanced Bio-Technologies, Incorporated 510(k) # K002488 and Silicone Scar Gel manufactured by MedTrade Products, Limited 510(k) # K014036

4.1.6 Device Description:

Beau Rx™ Scar Care Gel is a non sterile viscous emulsion/gel formulation, which is presented for over-the-counter use It is applied topically to aid in the management of both old and new Hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds

4.1.7 Packaging:

Beau Rx ™ Scar Care Gel comes in a 15 gram, 30 gram, and 50 gram labeled airless pump applicator, making it easy to apply to difficult areas It is safe, hygienic and easy to use It can be worn during the day or overnight

4.2.1 Sterilization:
The emulsion is supplied non-sterile

4.2.2 Intended Use:

Beau Rx™ Scar Care Gel is intended for the management of old and new Hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds

4.2.3 Summary of Technological Characteristics Compared to Predicate Devices:
Biocompatibility testing results are documented in Sections 21-25, Attachments I-V Additional documentation is provided in the FDA Drug Master Files found in Sections 26-28, Attachments VI-VIII Beau Rx Solutions product, Beau Rx™ Scar Care Gel, is substantially equivalent in design, composition, and function to Kelo-cote® manufactured by Advanced Bio-Technologies, 510(k) # K002488 and Silicone Scar Gel manufactured by MedTrade Products Ltd 510(k) #K014036 A table of comparative features is provided below for ease of review

4.2.4. Comparative Features Table:

COMPARATIVE FEATURES		
Characteristics:	**Beau Rx Solutions, LLC** **Beau Rx™ Scar Care Gel**	**Advanced Bio-Technologies, Inc.** **Kelo-cote® Scar Gel** **MedTrade Products, Ltd.** **Silicone Scar Gel**
Composition:	Self drying, topical emulsion made made from medical grade silicones	Self drying, topical emulsion made from medical grade silicones

Indication for Use:	For management of old and new Hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds	For management of old and new hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds
Sterilization Method:	Non Sterile	Non Sterile

4.3.1 Testing and Conclusion:

All required testing to assess the safety and efficacy of Beau Rx™ Scar Care Gel have been conducted and all results were satisfactory The testing results described in these summaries were performed individually on all specific materials used in Beau Rx™ Scar Care Gel

These summaries (Sections 21-25, Attachments I-V) are intended to serve as biocompatibility screenings Each summary contains the Summary of Health Data and Toxicology Testing of each ingredient used in Beau Rx™ Scar Care Gel Further data is provided in the FDA Drug Master File for review (Sections 26-28, Attachments VI-VIII) for each ingredient indicated

9.2.1 Comparative Features Table:

COMPARATIVE FEATURES		
Characteristics:	**Beau Rx Solutions, LLC** **Beau Rx™ Scar Care Gel**	**Advanced Bio-Technologies, Inc.** **Kelo-cote® Scar Gel** **MedTrade Products, Ltd.** **Silicone Scar Gel**
Composition:	Self drying topical emulsion made from medical grade silicones	Self drying, topical emulsion made from medical grade silicones
Appearance:	White gel	Clear translucent gel
Indication for Use:	For management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds	For management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds
Sterilization Method:	Non Sterile	Non Sterile

10. Device Description

10.1.1 Sponsor:

Beau Rx Solutions, LLC
1440 South Ocean Blvd #5C
Lauderdale by the Sea, Fl 33062

10.1.2 Contact:

Thomas L McGraw, President
Phone 1-954-817-6155
Fax 1-954-782-0018
E-mail Silospheres@bellsouth net
Date of Preparation October 15, 2008

10.1.3 Contract Manufacturer:

A I G Technologies
1917 N W 40th Court
Pompano Beach, Florida 33064
Reg #3003500617
Label Code 66756

10.1.4 Device Identification:

Proprietary Name Beau Rx™ Scar Care Gel
Common Name Silicone Scar Gel
Classification Name Elastomer, Silicone, for Scar Management
CFR 878.4025
Product Code MDA

10.1.5 Indications for Use:

Beau Rx™ Scar Care Gel is intended for the management of old and new scars including Hypertrophic and Keloid scarring on scars resulting from general surgical procedures, trauma wounds, and burns

Appearance:	White gel	Clear translucent gel
Indications for Use:	For management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds	For management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds
Sterilization Method:	Non Sterile	Non Sterile

10.3.1 Comparative Differences Table:

Characteristics:	Beau Rx™ Scar Care Gel	Kelo-cote® Scar Gel	Silicone Scar Gel
Film former and Adhesion Agents	ST-Dimethiconol 40, Dimethicone, and Silky Wax 10	Fumed Silicone Dioxide, a gelling or thixotropic agent	Fumed Silicone Dioxide, a gelling or thixotropic agent

10.3.2 Summary of Differences:

ST-Dimethiconol with Dimethicone provides the composition device with the ability to form a highly substantive mat film finish on the skin The Silky Wax 10 (Stearoxytrimethylsilane and Stearyl alcohol), acts as a hardening lubricant which causes a reduction in the elastic contribution of the gum blend under stress and a reduction in the creep of the film This combination of Silky Wax 10, Dimethicone, and ST-Dimethiconol 40 forms a film on the skin creating adhesion to the skin and substantivity to Beau Rx™ Scar Care Gel The predicate devices use Fumed Silicone Dioxide (fumed silica) as a gelling or thixothropic agent to stiffen the gel causing adhesion to the skin and film formation

10.3.3 Conclusion:

Beau Rx™ Scar Care Gel has the same intended use and similar technological characteristics as the predicate devices Moreover, the non-clinical testing and the predicate devise comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness Thus, Beau Rx™ Scar Care Gel is substantially equivalent to the predicate devices

11.2.1 Comparative Features Table:

COMPARATIVE FEATURES		
Characteristics:	**Beau Rx Solutions, LLC.** **Beau Rx™ Scar Care Gel**	**Advanced Bio-Technologies, Inc.** **Kelo-Cote® Scar Gel** **MedTrade Products, Ltd.** **Silicone Scar Gel**
Composition:	Self drying, topical gel made from medical grade silicones	Self drying, topical gel made from medical grade silicones
Appearance:	White, gel	Clear translucent gel
Indications for Use:	For management of old and new Hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures, and trauma wounds	For management of old and new Hypertrophic and Keloid scarring on scars resulting from burns, general surgical procedures, and trauma wounds
Sterilization Method:	Non Sterile	Non Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Beau Rx Solutions, LLC
% Mr Thomas L McGraw
1440 S Ocean Boulevard, Suite 5C
Lauderdale by the Sea, Florida 33062

JAN 2 6 2009

Re K083718
Trade/Device Name Beau RX™ Scar Care Gel
Regulation Number 21 CFR 878 4025
Regulation Name Silcone sheeting
Regulatory Class I
Product Code MDA
Dated October 15, 2008
Received December 15, 2008

Dear Mr McGraw

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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), 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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083718

Device Name Beau RX™ Scar Care Gel

Indications For Use

The Beau RX™ Scar Care Gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting for burns, general surgical procedures and trauma wounds

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off), Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K083718