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MAY 0 6 2013

Section 5
510(k) Summary

[As required by 21 CFR 807.92(c)]

Owner Name and Contact Details:
Andrew I. Sealfon, CEO & President
Repro-Med Systems, Inc. dba RMS Medical Products
24 Carpenter Road
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FDA Establishment Registration Number:
1318360

Prepared on:
August 2, 2012

510k Number:
K122404

Trade Name:
RMS HIgH-Flo™ Subcutaneous Safety Needle Sets

Classification Name:
Intravascular Administration Set

Classification Code:
FPA (per 21 CFR 880.5440)

Classification:
Class II

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Substantial Equivalence to Predicate Devices:

RMS Medical Products
Subcutaneous Needle Set
K102512

Evans Medical, Inc.
Evans Winged Sub-q MC4206
K020530

MarCal Medical, Inc.
Subcutaneous Needle Infusion Set
K082818

Device Description:
The RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are a Class II Intravascular Administration Set per 21 CFR 880.5440 and intended for the delivery of medication to the subcutaneous tissue. Each set consists of a sterile packaged kit including the infusion set and a commercially available adhesive dressing used to hold the device in place. The infusion set has a 90-degree stainless steel grade needle mounted to a butterfly assembly on one end, and a luer lock on the other end, connected by medical grade tubing. The needles are available in 24 and 26 gauges and in lengths of 4mm, 6mm, 9mm, 12mm and 14mm. The 4mm and 14mm lengths are added for children and obese adult patients, respectively. The optional convenience 24" Extension Set is used to add length to a needle set when desired.

There is a snap closure to safely capture the needle after use. This minimizes the potential for a needlestick injury. Each leg in a set is equipped with a slide clamp to stop flow immediately, if needed. The RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are available for up to 8 infusion sites using our basic sets of one, two, three or four legs ganged together using a low residual "Y-Connector" (for example to achieve a 7 site infusion, a RMS 4 set will be ganged with a RMS 3 set using a Y-Connector). All needle sets, regardless of combination, are for single use only.

Indications for Use:
RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are intended for the delivery of medication to the subcutaneous tissue. **There are no differences in the indications for use between the current RMS HIgH-Flo™ Safety Subcutaneous Needle Sets and the predicate RMS subcutaneous needles in K102512, or other predicate devices.**

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Summary of Data:
As stated in the cover letter and pertaining to the seven modifications to an already legally marketed RMS device (K102512), the additional test data that is included in this new submission to support new claims is summarized below:

Biocompatibility:
To remove the 24 hour (short-term) use limitation of the previous RMS subcutaneous needle set submission K102512, studies were performed in accordance with internationally recognized standards including: (1) *ISO Systemic Toxicity Study-Extract (Sodium Chloride)*, (2) *ISO Systemic Toxicity Study-Extract (Sesame Oil)*, and (3) *ISO Subcutaneous Implantation Study in Rabbits-6 weeks*. Results meet acceptable ISO criteria.

To include the term "non-pyrogenic" two studies were performed in accordance with internationally recognized standards: (1) *Pyrogen Study - Material Mediated*; (2) *Limulus Amebocyte Lysate*. Results of both studies were within acceptable USP limits, USP<151> and USP<85>, respectively.

We are including the studies submitted for the predicate RMS Subcutaneous Needle Set (K102512) that include cytotoxicity; irritation; sensitization, and hemocompatibility.

All studies, new and predicate, show the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are considered equal to, or better than, predicate devices.

Clinical Evaluation:
To claim "Safety" for the Needle Sets, medical professionals participated in an RMS Clinical Simulated Use Study, per FDA guidance documents with FDA review of the proposed protocol. An analysis of all subjective and statistical data concludes that the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets met the criteria set and thus may be classified as safety sets. Furthermore, all critical and essential tasks (as specified in the protocol) and difficulties with use of the product during the study were evaluated as part of this safety determination. No adverse effects or complications were reported during the study. Consequently, the device is known as "Safety" Needle Sets and has a safety design equal to, or better than, predicate devices.

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Device Characteristics:

Additional 4mm and 14mm needle lengths are used for children and obese adult patients, respectively, and are substantially equivalent in physical properties, material grade, and have similar indications for use as the predicate devices Evans (K020530) and MarCal (K082818). Both of these predicates include 14mm, and K020530 also includes 4mm. Thus, no new issues of safety or effectiveness are introduced.

Predicate Device Comparison Chart

Characteristic	RMS HIgH-Flo™ Subcutaneous Safety Needle Sets (New)	RMS Subcutaneous Needle Set K102512 (Predicate)	EMED®/Evans Sub-q Set K020530	MarCal Medical Sub-q Set K082818
Tubing Length (inches)	20, 24, *44	20	2, 4, 3.5, 5, 36, 42	36, 42
Tubing Material	Medical Grade PVC Plastic	Medical Grade PVC Plastic	Medical Grade Polyethylene Plastic	Medical Grade PVC Plastic
Needle Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Needle Gauge	24, 26	26	24, 27	24, 27
Needle Length (mm)	4, 6, 9, 12, 14	6, 9, 12	4, 6, 9, 12, 14	6, 9, 12, 14
Sterilization Method	Gamma	Gamma	ETO	ETO
Indications for Use	RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are intended for the delivery of medication to the subcutaneous tissue.	RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue.	Evans Winged Subcutaneous Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.	The Subcutaneous Infusion Set is designed specifically for the delivery of medication to the subcutaneous tissue.

*-- 44" is the full length with the optional convenience 24" Extension Set added

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Material Characteristics:

RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are comprised of either identical or equivalent medical grade materials as used in the RMS sets cleared under K102512, the Evans sets cleared under K020530, and the MarCal sets cleared under K082818. Thus, no new issues of safety or effectiveness are introduced.

Materials Comparison Chart				
	Female Luer	**Tubing**	**Butterfly**	**Adhesive Dressing**
RMS HIgH-Flo™ Subcutaneous Safety Needle Sets	PVC	PVC	Polypropylene	Dressing by 3M
RMS Subcutaneous Needle Set	PVC	PVC	Polypropylene	Dressing by 3M
Evans Sub-q Set	PVC	Polyethylene	PVC	Hypoallergenic dressing
MarCal Sub-q Set	NA	PVC	Polyethylene	NA

Performance Testing (flow rate):

Fluid flow rate testing was performed on the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets to determine performance with: (1) the addition of 7-needle and 8-needle sets; (2) the addition of a 24 gauge needle set; (3) the addition of an optional convenience 24" Extension Set. Testing was completed in accordance with an RMS internal procedure (SOP 8001). Results were compared with the predicate devices and are summarized below:

Overall Flow Comparison Results

Average Flow Rate (mL/hr) using D50 @ 5psi									
	Needle								
	1	2	3	4	5	6	7	8	Total
RMS Medical Products 26G	48.55	49.87	48.47	48.02	48.42	50.48	48.89	47.04	389.74
RMS Medical Products 24G	239.72	238.01	239.31	240.55	239.84	239.67	240.65	239.77	1917.52
Evans Medical 27G	24.64	22.55	12.97	24.33	27.96	26.57	n/a	n/a	139.02
Evans Medical 24G	50.32	50.18	49.18	48.40	n/a	n/a	n/a	n/a	198.09
Marcal Medical 24G	101.86	101.48	103.76	100.10	n/a	n/a	n/a	n/a	407.21
Marcal Medical 27G	34.36	67.82	95.56	126.04	n/a	n/a	n/a	n/a	323.78

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To determine the effects of the two additional insertion needles, a comparison test was completed using 26 gauge sets of all configurations up to 8-needles. The data was compared with a single 26 gauge needle set for total fluid flow output. Results of this comparison test show that the measured and compared data demonstrates that there is no degradation of flow when the 7th and 8th needles are added.

An additional test demonstrated no negative effect upon leg-to-leg consistency from adding the 7th and 8th needles.

To support the addition of a 24 gauge needle set, 24 gauge needle sets were flow tested, up to and including 8-needle set configurations, and compared with flow data from predicate devices which were measured up to six needle sites. Results indicate that the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets have equal or better flow performance than both the Evans and MarCal predicate devices. In comparison, the 26 gauge RMS HIgH-Flo™ Subcutaneous Safety Needle Sets flow better than the 27 gauge needles from the Evans and MarCal predicates. Also, the 26 gauge flows somewhat better than the Evans 24 gauge needle, but slower than the MarCal 24 gauge. In comparison, the 24 gauge RMS HIgH-Flo™ Subcutaneous Safety Needle Sets flow as well as, or better than, any of the listed predicate devices.

To further support this conclusion, a second test was completed in which the 24 gauge needle set was tested using the same method as the 26 gauge comparison test above, and a single 24 gauge needle set was compared with subsequent configurations with respect to total flow output. The test results indicate there was no degradation of flow rates with the additions of the 7th and 8th needles and the variation of flow from leg to leg was less than 7% for the 24 gauge needle sets.

In addition, the 24 gauge was tested using a 5cp viscosity fluid to simulate the flow of certain viscous drugs. Results confirm that these thicker drugs will flow as designed in the 24 gauge needle assemblies.

To support the addition of an optional convenience 24" Extension Set to provide additional length for the convenience of patients who are using the RMS 26 gauge needles, we conducted a flow test. This was to determine that the addition of the optional convenience 24" Extension Set would have (at most) a minor impact on flow rate and for most patients, and therefore would not be noticeable.

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Residual Volume Testing:
Priming/residual volumes were also measured for the use of additional sites and 24 gauge needles and data was compared with the predicate devices. The performance testing indicates that the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets have similar performance to the predicate devices specifically indicating substantially equivalency.

Data Revised:
Data revised since the predicate RMS submission K102512 that is included in this new submission, but does not affect the claims as stated in the cover letter, includes:

Sterilization and Shelf Life:
In accordance with ISO 11137, aging of the RMS High-Flo™ Subcutaneous Safety Needle Sets' packaging and product was completed for a three-year determination from a one year determination. Tests performed on the aged packaging and product included: dye migration; bag seal integrity; multi-port luer function and brittleness; needle/hub bond test; flexibility of [butterfly] wings; butterfly wing performance; luer/tube integrity. All results indicate that the integrity of the packaging and seal is acceptable and protects the device from degradation during three year aging and there is no degradation of the product. See Section 14 for details.

Data Unchanged:
Data unchanged since the predicate RMS submission K102512 and that is included in this new submission, but does not affect the claims as stated in the cover letter, includes:

Needle Tip Measurements:
A comparison of the needle tip dimensions indicates there is no substantial difference between the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets and the predicate devices.

Performance Testing:
Needle tip, stiffness, resistance to breakage and corrosion, conical fitting, and fatigue tests were completed for the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets and compared with the predicate devices.

Conclusion:
Considering all clinical and non-clinical data included in this 510(k) submission, the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are as safe, as effective, and perform equally to, or better than, predicate devices from RMS, Evans, and MarCal.

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Substantial Equivalence Statement:
All data presented demonstrates that the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are substantially equivalent to the predicate devices in terms of function, safety, performance, intended use, technology/principles, mechanical properties, biocompatibility, and flow. Differences between the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets and the predicate devices do not raise any new issues of safety or effectiveness.

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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

May 6, 2013

Mr. Andrew I. Sealfon
Chief Executive Officer & President
Repro-Med Systems, Incorporated, DBA RMS Medical Products
24 Carpenter Road
Chester, New York 10918

Re: K122404
Trade/Device Name: RMS High-Flo Subcutaneous Safety Needle Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 14, 2013
Received: March 21, 2013

Dear Mr. Sealfon:

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.

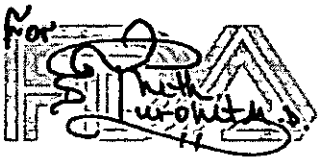
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit I

Section 4
Indications for Use Statement

510(k) Number (if known):	**K122404**
Device Name:	RMS HIgH-Flo™ Subcutaneous Safety Needle Sets
Indications for Use:	RMS HIgH-Flo™ Subcutaneous Safety Needle Sets are intended for the delivery of medication to the subcutaneous tissue.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Richard C. Chapman 2013.05.02 11:14:26 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122404