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# RMS Medical Products Receives FDA 510(k) Clearance for High-Flo Super26™ Subcutaneous Needle Sets

CHESTER, N.Y.--(BUSINESS WIRE)-- **Repro Med Systems, Inc. dba RMS Medical Products (OTCQX: REPR) (RMS Medical)** today announced that it has received 510(k) clearance from the U.S. [Food and Drug Administration \("FDA"\)](#) for its High-Flo Super26™ Subcutaneous Needle Sets ("Super 26 Needle Sets").

The Super26 Needle Sets are indicated for subcutaneous infusion of medications in the home, hospital, or ambulatory settings to facilitate high flow rates, including human plasma-derived immunoglobulins such as Hizentra® and Cuvitru™. Expanding on RMS Medical's well-regarded lineup of High-Flo needle sets, the Super26 Needle Sets utilize a proprietary design to provide 26-gauge comfort with significantly faster flow rates. The Super26 Needle Sets will be offered as a single-needle set, as well as 2-needle, 3-needle, 4-needle, 5-needle, 6-needle sets; through use of a Y-connector, 7-needle and 8-needle sets may also be assembled. The sets will be available as part of RMS Medical's Freedom Integrated Infusion System, the only fully-integrated mechanical system cleared by the FDA for a wide range of medications and flow rates.

"This clearance reflects our commitment to broadening RMS Medical's product portfolio with solutions that optimize the delivery and efficacy of subcutaneous therapies, promote compliance, and improve the overall patient experience," said Don Pettigrew, President and Chief Executive Officer. "The Super26 Needle Sets support the shift towards faster SCIg infusions while addressing patient comfort concerns via the use of a smaller diameter needle. This could be very helpful in existing and new indications where large volumes of drugs are required to be infused."

"RMS Medical continues to define itself as an industry leader," said Daniel Goldberger, Executive Chairman. "New product introduction is an important component of our previously announced strategic plan. As we advance towards our vision of becoming *the preferred drug delivery partner for specific infusion therapies in select markets*, we will continue to focus on delivering innovative solutions to our growing industry."

## Forward-looking Statements

The statements contained herein include prospects, statements of future expectations and other forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on management's current views and assumptions and involve known and unknown risks and uncertainties, identified by words such as "are expected" and "will". Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements. Factors that may cause actual

results to differ materially from current expectations and other risks are discussed in RMS Medical's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K, which filings are available from the SEC and RMS Medical's website. RMS Medical undertakes no obligation to update any forward-looking statements.

### **About RMS Medical Products**

RMS Medical develops, manufactures and commercializes innovative and easy-to-use specialty infusion solutions that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System currently includes the FREEDOM60<sup>®</sup> and FreedomEdge<sup>®</sup> Syringe Infusion Drivers, RMS Precision Flow Rate Tubing<sup>™</sup> and RMS HlgH-Flo Subcutaneous Safety Needle Sets<sup>™</sup>. These devices are used for infusions administered in the home and alternate care settings. For more information about RMS Medical, please visit [www.rmsmedicalproducts.com](http://www.rmsmedicalproducts.com).

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