510(k) SUMMARY

17 September 2007

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Trade Name: **AutoloGel™ System**

Sponsor: Cytomedix, Inc.
416 Hungerford Drive
Suite 330
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FDA Registration #- 3004140833

Device Generic Name: **Wound Dressing**

Classification: Unclassified, according to Section 513 of the Federal Food, Drug, and Cosmetic Act

Product Code: MGQ

Product Description:

The AutoloGel™ System is a device consisting of a table top centrifuge (AutoloGel II Centrifuge) and a wound dressing convenience kit (AutoloGel Wound Dressing Kit) comprised of legally-marketed products, i.e., blood access and processing devices, USP-grade reagents (ascorbic acid, bovine thrombin, calcium chloride and ACD-A anticoagulant).

The AutoloGel System uses the patient's own plasma, platelets, and other blood components. The patient's blood components are separated through high-speed centrifugation by the AutoloGel II Centrifuge to derive platelet-rich plasma (PRP). The patient's platelet-rich plasma is mixed with ascorbic acid and calcified thrombin (bovine). This process changes the liquid PRP to a gel consistency, AutoloGel.

AutoloGel is applied to the wound under the supervision of a licensed healthcare practitioner. The gel may assist the natural healing process by maintaining a moist wound environment.

Indications for Use:

The AutoloGel™ System is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient's own blood. Under the supervision of a healthcare professional, the PRP gel produced by the AutoloGel™ System is suitable for exuding wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and for the management of mechanically or surgically-debrided wounds.

Predicate Devices:

Similar to the Harvest Technologies PRP separation system (BK000037), the Autologel system is intended for the preparation of platelet-rich plasma (PRP), from a small sample of the patient's own blood at the point of care. The intended use of the AutoloGel System is to produce autologous PRP for wound management, and is substantially equivalent to the predicate wound dressing/gel, IPM Wound Gel (K020325).

Clinical Performance:

Cytomedix has submitted preclinical and clinical data from studies with the AutoloGel System.

Clinical Trial:

A prospective, randomized, double blinded, multi-center, controlled clinical trial of diabetic foot ulcers was conducted in 14 investigational sites and in accordance with the Agency's IDE regulations for investigational devices.

Efficacy

The Cytomedix clinical trial outcomes and results from the Per Protocol Analysis demonstrated that the majority 35/40 (88%) of the diabetic foot ulcers in the study had a wound area ≤ 7 cm^2. In the Per Protocol, ≤ 7 cm^2 wound dataset, AutoloGel™ treated wounds had statistically significant healing over control treated wounds, 81.3% vs 42.1%, respectively ($p = 0.036$). When all patient wounds of all sizes were analyzed, AutoloGel achieved 68.4% healing in the AutoloGel treatment group and 42.9% healing in the control treatment group (not statistically significant).

Safety

The AutoloGel System was evaluated in a prospective, randomized, double- blinded, multi-center controlled clinical trial on diabetic foot ulcers with 72 patients; 40 of whom were treated with AutoloGel at fourteen (14) investigative sites. Safety parameters were evaluated during the 12 weeks of treatment and the three month follow-up period.

No serious adverse events related to the AutoloGel System treatment have been reported. However, 23 unrelated serious adverse events occurred in the study: six (6) in five (5) AutoloGel patients and seventeen (17) in seven (7) control group patients.

Conclusions:

Cytomedix has compared the technological characteristics of the AutoloGel System and its components to predicate wound dressing / gels. This 510(k) information has demonstrated that the technological characteristics of the AutoloGel System are substantially equivalent to those of the cited predicates IPM Wound Gel and Harvest Technologies' table top centrifuge with regard to it's ability to produce autologous PRP at the point of care from a small sample of the patient's own blood.

Cytomedix conducted a prospective, randomized, blinded, multi-center, controlled trial that demonstrated the clinical performance and the safety of AutoloGel when used for the management of chronic wounds. Based on the clinical performance information, it can be concluded that AutoloGel is substantially equivalent to the marketed wound dressing IPM Wound Gel.

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