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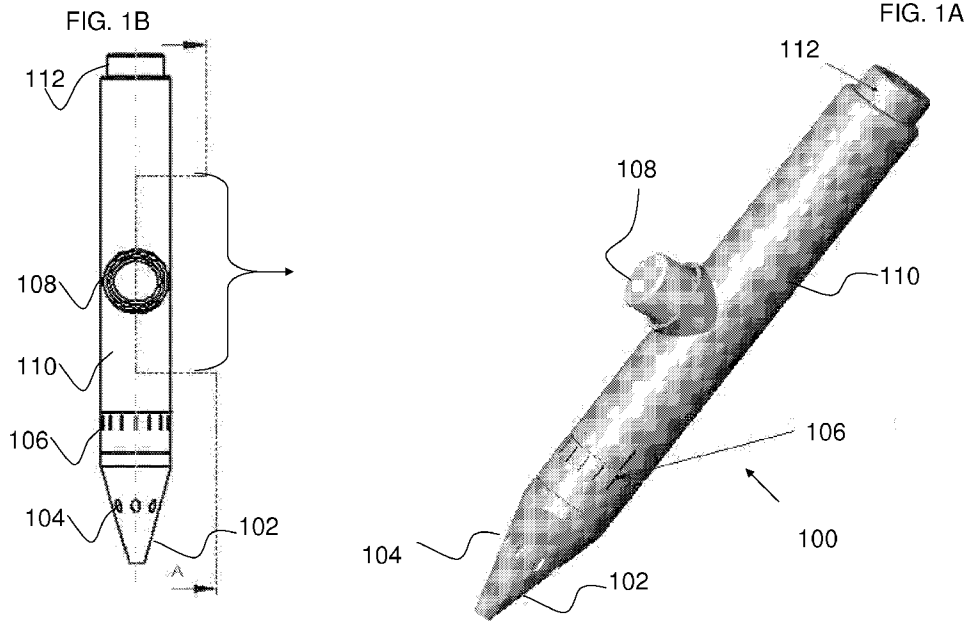
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(54) Title: DRUG DELIVERY DEVICE



(57) Abstract: The present disclosure presents systems, devices and methods for injection of drugs, substances and/or chemicals to a patient and for improving their effectiveness once they are injected are disclosed. Additional treatment can be applied to a tissue region on the patient into which a drug (e.g., insulin) is injected, to expose the tissue region to various forms of energy or a substance to improve the drug's pharmacokinetic and/or pharmacodynamic profile.

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## DRUG DELIVERY DEVICE

### CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present invention claims priority to U.S. Provisional Patent Application No. 60/895,518, filed March 19, 2007, U.S. Provisional Patent Application Serial No. 60/895,519, filed March 19, 2007, U.S. Provisional Patent Application Serial No. 60/912,698, filed April 19, 2007, U.S. Provisional Patent Application Serial No. 60/940,721, filed May 30, 2007, U.S. Provisional Patent Application No. 61/016,571, filed December 25, 2007, U.S. Provisional Patent Application No. 61/008,277, filed December 18, 2007 and U.S. Provisional Patent Application No. 61/010,758, filed January 10, 2008, and U.S. Patent Application Serial 11/812,230, filed June 21, 2007, , the disclosures of which are incorporated herein by reference in their entireties.

### BACKGROUND OF THE INVENTION

#### Field of the Invention

[0002] The present invention relates to systems and methods for delivering drugs to a patient. In particular, the present invention relates to systems and methods for subcutaneous injection of a medicament and using one or more treatment sources to improve effectiveness of the injected drugs.

#### Background of the Invention

[0003] Pen injectors are useful when regular injection by persons without formal medical training occurs. This is increasingly common amongst those having chronic conditions such as diabetes where self-treatment enables such persons effectively manage their condition. Many of the insulin pen injectors are reusable and usually loaded with an insulin cartridge that may be used for a plurality of injections or for a number of days. Many other diabetic patients use regular syringe(s) and needles for insulin injection.

[0004] Diabetes is a very serious illness affecting millions of people today. Many diabetic patients require injections of insulin to maintain proper levels of glucose in their blood in order to survive. Such injections of insulin require drug injection systems.

[0005] Many medical treatment systems and methods involve drug injection systems that employ subcutaneous injections of therapeutic fluids, drugs, proteins, and other compounds. Such delivery systems and methods, especially for insulin delivery, may use injection pens to inject insulin to the subcutaneous tissue, or regular syringe. In the conventional insulin injection pens, the pen includes a disposable insulin reservoir and a disposable needle through which insulin is injected into the tissue. The needle is a single use needle, while the insulin reservoir can be used for two to three days. In the conventional insulin injection pens, the injection is done by attaching the insulin injection pen to the skin at the injection site and pressing a button that first insert the needle using a spring into the subcutaneous tissue and then inject the insulin to the subcutaneous tissue.

[0006] In many instances, the patients require insulin injection around the clock to keep proper levels of glucose in their blood. Two major types of insulin can be injected – a long-acting insulin that provides the basal insulin rate needed for keeping patient’s blood glucose in the desired range between meals and over night and an insulin bolus injection that provides an amount of insulin for matching a dose of carbohydrates consumed by the patient.

[0007] When patient consumes food, his or her levels of glucose rise. Unfortunately, many conventional subcutaneous injection devices are incapable of quickly matching and/or preventing the rise of blood glucose. The delay in such matching is also true in case of the “rapid-acting” insulin. Some of the reasons for this delay include a lag in the absorption of insulin from the injection site and the time it takes for complex insulin molecules to break down into monomers.

[0008] Additionally, since blood glucose levels rise shortly following the meal, the delay in matching insulin to the rising levels causes post prandial hyperglycemic events (i.e., when levels of blood glucose are above normal) to occur. Occasionally, after certain period of time passes (e.g., 2-3 hours) after the meal, the blood glucose levels drop yet insulin concentrations in the blood rise followed by the peak of the systemic insulin effect and may result in causing hypoglycemic events (i.e., when levels of blood glucose are below normal) to occur. Both hyperglycemic and hypoglycemic events are highly undesirable. Additionally, since local blood perfusion at the insulin injection region has large variability, depending on

the ambient temperature and other parameters, it induces large variations to the delay of the peak of time profile of the insulin action. Those variations in the insulin peak action period further increase the variability in the blood glucose level.

**[0009]** Thus, it is desirable to provide a system and a method that provides efficient and rapid injection and absorption of the drug to the patient circulatory system. In particular, it is desirable to provide a system and a method for injection of insulin to the patient that improves effectiveness of insulin in the blood to maintain normal levels of blood glucose and prevent or reduce hyperglycemic and hypoglycemic events.

#### SUMMARY OF THE INVENTION

**[0010]** The present invention relate to systems, devices and methods for injecting a drug, substances and/or chemicals to a patient that further provides a tissue treatment element for improving the effectiveness of drug delivery upon injection. In some embodiments, the present invention relates to a device for improving performance of drug delivery in the form of injection pens or syringes. In general, the present invention's suggested methods and devices can be used in many drug injection devices, such as injection pen(s), syringe(s), or jet injector(s), or other injection devices. As such, although the present application discusses mainly injection pens, it is understood by one skilled in the art that such devices can be used with any other injection devices. In some embodiments, the present invention provides for a device that further provides an additional treatment to a tissue region where the drug is delivered. In some embodiments, the treatment is utilized to improve drug delivery process by improving the drug's pharmacokinetic and/or pharmacodynamic profile. The treatment may come in various forms, for example, including analgesic, vasodilator or the like. The treatment may be any form of treatment that leads to improved vasodilatation of the tissue being injected, including but not limited to, exposing the tissue region to an energy, radiation, heat, mechanical vibrations, suction, massaging, acoustic stimulation, electromagnetic radiation, electric field, magnetic field, electrical stimulation, injection of an additional substance(s), or any combination of the above to improve the drug's pharmacokinetic and /or pharmacodynamic profile. Each treatment type may have a separate protocol in order to evoke the necessary reaction such as vasodilatation or the like.

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