

Along the top of the cavity are 12 springs which are used to force the micro needles into the skin. Also there is a solenoid that releases the spring. Each spring presses on the top of one of the 12 disposable components.

One end of each of the assay device fingers forms a hinge within the assay device, so the spring forces the assay device down through a layer of film, which covers the bottom of the assay device.

The optical fiber passes over the hinge and terminates at an optical splitter, which is mounted on the bottom of the electronics printed circuit board. The interface between the assay device and the assay reader device is a small air gap.

This end view of one of the 12 assay device fingers shows the package. The assay device is inside a sterile patch package. Under the micro needles there is a portion of the patch that is designed to allow the needles to penetrate and enter skin. The patch is held in place with an adhesive as shown in FIG. 6. Finally there is a protective cover. The top of the patch is designed to allow insertion into the reader. The optical signal passes through a portion of this seal between the end of the fiber and the splitter.

In this disclosure there is described only the preferred embodiments of the invention and but a few examples of its versatility. It is to be understood that the invention is capable of use in various other combinations and environments and is capable of changes or modifications within the scope of the inventive concept as expressed herein. Thus, for example, those skilled in the art will recognize, or be able to ascertain, using no more than routine experimentation, numerous equivalents to the specific substances and procedures described herein. Such equivalents are considered to be within the scope of this invention, and are covered by the following claims.

What is claimed is:

1. An ingestible medical device having an exterior surface and an interior surface, said ingestible medical device comprising:

- (a) a microarray comprising a polypeptide bioactive agent capable of interacting with a disease marker biological analyte, and further comprising a plurality of reaction sites on a continuous surface, each site of said plurality comprising affixed thereto the polypeptide bioactive agent;
- (b) a reservoir comprising a therapeutic agent;
- (c) a microchip comprising:
  - i) an optical microarray scanning device that is configured to optically detect signals from the plurality of reaction sites on the continuous surface, wherein the signals are indicative of a physical parameter representing an interaction between the disease marker biological analyte with said polypeptide bioactive agent at said plurality of reaction sites;
  - ii) a biometric recognition device that is configured to compare said physical parameter data with an analyte interaction profile;
  - iii) a therapeutic agent releasing device that is configured to control release of said therapeutic agent from said reservoir; and
  - iv) an interface device that is configured to facilitate communications between said microarray scanning device and said biometric recognition device; and
- (d) a biocompatible polymer coating, coated on the exterior surface of said ingestible medical device.

2. The medical device of claim 1, wherein the biocompatible polymer coating has channels.

3. The medical device of claim 1, wherein the biocompatible polymer coating is porous.

4. The medical device of claim 1, wherein the microarray comprises microbeads.

5. The medical device of claim 1, wherein the bioactive agent is an immunoglobulin.

6. The medical device of claim 1, wherein the bioactive agent is fluorescently labeled.

7. The medical device of claim 1, wherein the bioactive agent is fluorescently labeled with a nanocrystal.

8. The medical device of claim 1, wherein the disease marker biological analyte is a polypeptide.

9. The medical device of claim 8, wherein the disease marker biological analyte is an immunoglobulin.

10. The medical device of claim 1, wherein the microchip comprises silicon germanium.

11. The medical device of claim 1, wherein the microarray scanning device comprises fiber optic elements.

12. The medical device of claim 1, wherein the analyte interaction profile is stored on an external device separate from the medical device.

13. The medical device of claim 1 having a plurality of reservoirs.

14. The medical device of claim 1, wherein the interface device comprises a personal area network.

15. The medical device of claim 1 further comprising an energy source to power the medical device.

16. The medical device of claim 15, wherein the energy source is provided by a personal area network.

17. The medical device of claim 1, further comprising an osmotic pump.

18. The medical device of claim 1, further comprising pressurized microfluidic channels.

19. The medical device of claim 1, further comprising Personal Area Network transmitters directing the flow of bodily fluid.

20. The medical device of claim 1, wherein the medical device comprises one or more disposable components.

21. The medical device of claim 1, wherein said biometric recognition device controls said therapeutic agent releasing device.

22. The medical device of claim 1, wherein said biometric recognition is configured to store said physical parameter data and is configured to build a pharmacokinetic database of accessible analyte interaction profiles from said stored physical parameter data.

23. The medical device of claim 1 wherein the therapeutic agent is specific to a toxin or disease.

24. The medical device of claim 1 wherein the therapeutic agent is selected based on the detected disease marker biological analyte.

25. The medical device of claim 23 wherein the controlled release of the therapeutic agent is based on a detected concentration of the disease marker biological analyte.

26. The medical device of claim 1 wherein the microarray is configured to automatically interact with a gastric fluid when ingested by the subject.

27. The medical device of claim 26 wherein the medical device is configured to transmit information of said interaction to an external source.

28. The medical device of claim 1 wherein the plurality of the reaction sites are simultaneously exposed to a sample suspected to contain the disease marker biological analyte upon ingestion by the subject.

29. The medical device of claim 1 wherein the microarray scanning device is a camera.