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medexinc

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510(k) SUMMARY FOR MEDEX MEDFUSION 2001, 2010, & 2010i WITH NEW MICROPROCESSOR/MEMORY SYSTEM

The following summary of safety and effectiveness information is provided as required by Section 807.92(c) of the Safe Medical Devices Act of 1990.

Submitter	Medex, Inc.
Contact person	James W. Lewis
Summary prepared	22 April 1996
Trade names	Medfusion 2001, 2010, & 2010i
Common name	Syringe pump
Classification name	Infusion pump (per 21 CFR 880.5725)
Predicate devices	The legally marketed devices to which these new devices are equivalent are the previous products marketed by Medex under the same trade names
Device description	The new model Medex Medfusion Series 2000 pumps are identical to their predicate models with the exception that the microprocessor/memory chip is replaced by a drop-in replacement microprocessor–EPROM daughter board and that associated memory addresses in the software are modified to accommodate the hardware change. The exterior surfaces are made of plastics. There are no fluid or drug contacting surfaces.
Intended use	The intended medical application of Medex Medfusion 2000 Series syringe pumps is to produce controlled movement of the plunger of a syringe to inject a set amount of therapeutic fluid into a patient within a hospital setting at a set rate and at set times.
Technological characteristics	The basic design, material, chemical composition, and energy sources are the same as for the current corresponding Medex Medfusion model pumps. They are identical in operation, function, features, and form as their predicate devices and represent no technological differences.

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