

Indications for Use (CBER/OTAT)

510(k) Number (if known): BK180198

Device Name: AXP II AutoXpress Platform

Indications for Use:

The ThermoGenesis AXP II AutoXpress Platform is a cord blood processing system intended for laboratory use in combination with a specific and compatible single-use separation kit supplied by ThermoGenesis. The AXP II system allows the fast, automated, and reproducible separation of cord blood in a closed and sterile environment.

Prescription Use AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Tissues and Advanced Therapies

Office Sign-Off
Office of Tissues and Advanced Therapies

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