

**U.S. Food and Drug Administration****CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**[FDA Home Page](#) | [Contact eHCTERS Technical Support](#)**HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query  
Establishment Details**

## Establishment Name and Location

Current Status: Registered  
 Last Annual Registration Year: 2018  
 FDA Establishment Identifier (FEI): 3013188515  
 Establishment Name: HealthLink International Inc.  
 Address: 3655 Knight Road  
 Suite 1-3  
 City: Memphis  
 State: Tennessee  
 Zip: 38118  
 Country: United States  
 Phone: 18773242837

## Establishment Functions

|    | Types of HCT/P's                | Recover | Screen | Test | Package | Process | Store                               | Label                               | Distribute                          |
|----|---------------------------------|---------|--------|------|---------|---------|-------------------------------------|-------------------------------------|-------------------------------------|
| a. | Bone                            |         |        |      |         |         | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| b. | Cartilage                       |         |        |      |         |         | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| c. | Cornea                          |         |        |      |         |         |                                     |                                     |                                     |
| d. | Dura Mater                      |         |        |      |         |         |                                     |                                     |                                     |
| e. | Embryo                          |         |        |      |         |         |                                     |                                     |                                     |
| f. | Fascia                          |         |        |      |         |         |                                     |                                     |                                     |
| g. | Heart Valve                     |         |        |      |         |         |                                     |                                     |                                     |
| h. | Ligament                        |         |        |      |         |         | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| i. | Oocyte                          |         |        |      |         |         |                                     |                                     |                                     |
| j. | Pericardium                     |         |        |      |         |         |                                     |                                     |                                     |
| k. | Peripheral Blood Stem Cells     |         |        |      |         |         |                                     |                                     |                                     |
| l. | Sclera                          |         |        |      |         |         |                                     |                                     |                                     |
| m. | Semen                           |         |        |      |         |         |                                     |                                     |                                     |
| n. | Skin                            |         |        |      |         |         |                                     |                                     |                                     |
| o. | Somatic Cell Therapy Products   |         |        |      |         |         |                                     |                                     |                                     |
| p. | Tendon                          |         |        |      |         |         | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| q. | Umbilical Cord Blood Stem Cells |         |        |      |         |         |                                     |                                     |                                     |
| r. | Vascular Graft                  |         |        |      |         |         |                                     |                                     |                                     |

## Establishment HCT/P Listing

| Types of HCT/P's | HCT/P's Described in 21 CFR 1271.10 | HCT/P's Regulated as Medical Devices | HCT/P's Regulated as Drugs or | Proprietary Names |
|------------------|-------------------------------------|--------------------------------------|-------------------------------|-------------------|
|                  |                                     |                                      |                               |                   |

|    |                                 |   |  | <b>Biological<br/>Drugs</b> |  |
|----|---------------------------------|---|--|-----------------------------|--|
| a. | Bone                            | X |  |                             |  |
| b. | Cartilage                       | X |  |                             |  |
| c. | Cornea                          |   |  |                             |  |
| d. | Dura Mater                      |   |  |                             |  |
| e. | Embryo                          |   |  |                             |  |
| f. | Fascia                          |   |  |                             |  |
| g. | Heart Valve                     |   |  |                             |  |
| h. | Ligament                        | X |  |                             |  |
| i. | Oocyte                          |   |  |                             |  |
| j. | Pericardium                     |   |  |                             |  |
| k. | Peripheral Blood Stem Cells     |   |  |                             |  |
| l. | Sclera                          |   |  |                             |  |
| m. | Semen                           |   |  |                             |  |
| n. | Skin                            |   |  |                             |  |
| o. | Somatic Cell Therapy Products   |   |  |                             |  |
| p. | Tendon                          | X |  |                             |  |
| q. | Umbilical Cord Blood Stem Cells |   |  |                             |  |
| r. | Vascular Graft                  |   |  |                             |  |

## HCT/P Listing - Donor Information

|    | Types of HCT/P's                | SIP | Directed | Anonymous | Autologous | Family Related | Allogeneic |
|----|---------------------------------|-----|----------|-----------|------------|----------------|------------|
| e. | Embryo                          |     |          |           |            |                |            |
| i. | Oocyte                          |     |          |           |            |                |            |
| k. | Peripheral Blood Stem Cells     |     |          |           |            |                |            |
| m. | Semen                           |     |          |           |            |                |            |
| o. | Somatic Cell Therapy Products   |     |          |           |            |                |            |
| q. | Umbilical Cord Blood Stem Cells |     |          |           |            |                |            |





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