

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3003828812	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:28-DEC-2017 DISTRICT: Int'l Operations Group PRINTED BY FDA:27-JAN-2018
---	--	--	---

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
	Types of HCT / Ps	Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Hans Biomed Corporation 64, yuseong-daero 1628 beon-gil Youseong-gu Daejeon, 34054 Korea, Republic Of a. PHONE 822-466-2266 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3003828812) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X		X	X	X	X	X	X	X		*** See full text on next page
	b. Cartilage												
	c. Cornea												
5. ENTER CORRECTIONS TO ITEM 4	d. Dura Mater												
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia		X		X	X	X	X	X	X	X		Bellagen-F
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Hans Biomed Corporation Attn: Lucy Choi c/o Calways 105 Welker Ct Campbell, California 95008 a. PHONE 408-676-9063 EXT _____	g. Heart Valve												
	h. Ligament		X		X	X	X	X	X	X	X		
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	j. Pericardium												
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera												
8. U.S. AGENT Shane Liu, RAC Calways International, LLC 105 Welker Ct, Campbell, California 95008 a. E-MAIL fda@calways.net 408-676-9063	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	n. Skin		X		X	X	X	X	X	X	X		*** See full text on next page
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lucy Choi b. E-MAIL fda@calways.net c. TITLE Regulatory Affairs Manager d. DATE 28-DEC-2017	p. Tendon		X		X	X	X	X	X	X	X		
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft												
	s.												
	t.												
	u.												
	v.												

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3003828812

2

ADDITIONAL INFORMATION:

Additional Proprietary Names:

a. Bone: D-SureChip, Exponent, Vivex DBM Plus, Purebone, ExOss,
ExOss Plus, HC Chip, CortiOss, CortiOss-D, ConiOss

Proprietary Name(s):

a. Bone SureOss, OsteoGrow, SureChip, SureBlock, Genesis,
Pedi-Stick, INGROSS, CANOSS, OsteOss, ExFuse,
SurFuse, D-SureBlock
n. Skin Belloderm, Bellagen, SureDerm, Sheba, RegenCell,
AlloCover, GPS, CPS