Attachment 5

FDA ANIMAL PRODUCTS DATABASE

For each animal derived product device, fill out one DEVICE IDENTIFICATION form.
For each animal product or component in the device, fill out one MATERIAL INFOMATION form

DEVICE IDENTIFICATION INFORMATION

Manufacturer name:_____
Submission number:_____ ODE division_____
Generic Device Name:_____
Model Identifier or trade name:_____
Implantation or Tissue contact Duration:
( ) less than 24 hours ( ) 24 hours to 30 days ( ) greater than 30 days

FROM THE LISTS BELOW, circle the most appropiriate:

1. **generic organ system with which the device makes contact**
2. **tissue with which the device makes contact**
3 & 4. **form of packaging and sterilization used.**

ORGAN SYSTEM

cardiovascular
dental
ear
endocrine
gastrointestinal
musculoskeletal
neurokogical
ophthalmic
pulmonary
reproductive
soft tissue
urogenital
other:

TISSUE CONTACT

bladder
blood
bone
brain/CNS
breast
gastric
gingival
heart
joint
kidney
liver
lung
muscle
ocular
oral mucosa
pulmonary
rectum
reproductive, female
reproductive, male
skin
subcutaneous
synovial
teeth
vascular
other:

PACKAGING & STERILIZATION

bubble wrap
double blister pack
foam bubble
inert gas pack
single blister pack
none
other:

chlorine dioxide
dry heat
electron-beam
ethylene oxide (ETO)
filtration
gamma radiation, in air
gamma radiation, inert gas
hydrogen peroxide
solution sterilized
steam
not sterile
other:

MATERIAL AND ANIMAL PRODUCT INFORMATION

Using the tables below, indicate the animal product, species country of origin, and other indicated information

one form for each product or component in the device

TISSUES, CELLS, & BIOMOLECULES (select one)

TISSUES:	BIOMOLECULES:
blood vessel	*agar*
bone	*albumin*
cartilage	*alginate*
coral	*BMP*
cornea	*cellulose*
dura mater	*chitosan/chitan*
fascia lata	*chondroitin sulfate*
fibrous sheath	*collagen*
heart valve	*elastin*
joint	*fibrin*
ligament/tendon	*fibrinogen*
pericardium	*fibronectin*
umbilical cord	*gelatin*
umbilical vein	*growth hormones*
viscera	*heparin*
*other*_____	*hyaluronic acid*
	hydroxypropylmethylcellulose
CELLS:	*insulin*
adipocyte	*molluscan glue*
bone marrow	*PHB*
chondrocyte	*pituitary extract*
endothelial	*phospholipid*
epithelial	*polyaminoacid*
fibroblast	*protein extract*
hepatocyte	*RGD protein*
islet	*saline*
keratinocyte	*serum*
osteoblast	*silk*
renal tubular prog.	*triglycerides, soy bean oil*
smooth muscle	*trypsin*
*other*_____	*other*_____

SPECIES

- *bacterial*
- *bat*
- *bovine (cow)*
- *caprine (goat)*
- *chicken*
- *coral, scleractinia*
- *equine (horse)*
- *feline (cat)*
- *fish*
- *fungal/synthetic*
- *hamster*
- *human, allograft*
- *human, self*
- *insect*
- *kangaroo*
- *lapine (rabbit)*
- *mollusk*
- *monkey*
- *murine (mouse)*
- *ovine (sheep)*
- *plants*
- *porcine (pig)*
- *rat*
- *shark*
- *snake*

COUNTRY OF ORIGIN?

*name:*_____

is the material bioresorbable?

( ) yes ( ) no

STARTING FORM: was the biological product: ?
(circle one)

- *purified*
- *recombinant*
- *synthetic*

FORMING & PROCESSING
were any of these processes utilized during fabrication of the component?
(circle all that apply)

cell/tissue culture	*cross-linked*
mandrel grown	*enzyme treatment*
cyropreserved	*fixation, chemical*
cell seeded	*viral inactivation*
TDMAC	*demineralize*
*other*_____	*hydrothermal conversion*