



FDA | **U.S. Food and Drug Administration**
FURLS | **Device Registration & Listing**

Registered Facilities:

Facility Name:

NANTONG JINYUAN INTELLIGENCE MANUFACTURING TECHNOLOGY CO., LTD

Facility Address:

NO.20 QIXIN ROAD .DEVELOPMENT ZONE, NANTONG, JIANGSU 226000 CHINA

Owner/Operator Number :

10081505

Device Listings:

Listing Number: D442197

Product Code (s) : EJH

Device Name: ALLOY, METAL, BASE

Proprietary Name : Ti6AL4V DENTAL ALLOY POWDER
COBALT CHROMIUM ALLOY POWDER

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Created Date: Jan. 05, 2022
Registration Expiration Date: Dec. 31, 2022



JINYUAN

JINYUAN

CoCrW
dental
alloy
Powder

The manufacturer certifies that the dental srm alloy provided to the laboratory with this certificate is FDA-listed CoCrW dental alloy powder.

Material/Manufacturer

Nantong Jinyuan Intelligence Manufacturing Technology Co.,Ltd.

Material/Composition

Co	61.5%
Cr	27.75%
W	8.5%
Si	1.5%
Fe	0.50%
Mn	0.25%



Add: No.20 Qixin Road, Economic-Technological Development Area, Nantong, Jiangsu Province, China

Tel: +86-0513-80950066 Fax: +86-0513-80950065

中华人民共和国医疗器械注册证

注册证编号：国械注准20203170788

注册人名称	南通金源智能技术有限公司
注册人住所	南通市开发区齐心路20号
生产地址	南通市开发区齐心路20号
代理人名称	/
代理人住所	/
产品名称	牙科用激光选区熔化钴铬合金粉
型号、规格	规格：1kg/瓶、5kg/瓶
结构及组成	本产品为微米级粉末，由钴（Co）61.50%、铬（Cr）27.75%、钨（W）8.50%、硅（Si）1.50%、铁（Fe）≤0.50%、锰（Mn）≤0.25%成分组成。
适用范围	钴铬合金粉末适用于通过3D打印激光选区熔化（SLM）技术加工牙科修复体，可用于制作嵌体、冠、桥、可摘局部义齿支架及卡环。
附件	产品技术要求
其他内容	/
备注	

审批部门：国家药品监督管理局

批准日期：二〇二〇年十月九日

有效期至：二〇二五年十月八日