Special Reporting Project for a Medical Device Manufacturer

1. Objective

Client seeks information regarding competitors and potential acquisitions in the medical device industry. The pertinent data is publicly available from two sources: the FDA 510k applications database, and the FDA medical devices database. However, although the data is freely available, there are no existing tools in the market that will provide the custom queries and display output that the client desires. Additionally, all software must be web-based.

2. Proposed Solution
    2.1. Data Acquisition and Transformation
        • Contractor to download the publicly available CSV file sources, import them into Microsoft SQL and optimize the database indexes for fast data retrieval
    2.2. Add functionality to existing websites owned / managed by the contractor.
        2.2.1. Query Tools
        • Create web-based applications for custom query form input, data preview and CSV export.

3. Data Sources
    3.1. 510ks
        http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm
    3.2. Medical Device Listings:
        http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm134495.htm

4. Technologies
    o   CSV formatted text files (for FDA source data and exports)
    o   Microsoft SQL database server
    o   ColdFusion application server
    o   Windows Server

5. CSV Export Data Fields and Field Order
    5.1. 510ks

Table	Field	Export Column
cdrh_510k_approvals	CDRH_510k_Number	510(k) Number
cdrh_510k_approvals	CDRH_510k_Type	Type
cdrh_510k_approvals	Product_Code	Product Code
cdrh_510k_approvals	Device_Name	Proprietary Device Name
Product_codes	Common_Device_Name	Common Device Name
cdrh_510k_approvals	Advisory_Committee	Panel
cdrh_510k_approvals	Third_Party	Third Party Reviewed
cdrh_510k_approvals	Expedited_Review	Expedited Review

Special Reporting Project for a Medical Device Manufacturer

cdrh_510k_approvals	Date_Received	Application Date
cdrh_510k_approvals	Decision_Date	Decision Date
cdrh_510k_approvals	DECISION	Decision
cdrh_510k_approvals	Summary_Statement	Summary or Statement
cdrh_510k_approvals	APPLICANT	Company Name
cdrh_510k_approvals	CONTACT	Contact Name
cdrh_510k_approvals	STREET1	Address 1
cdrh_510k_approvals	STREET2	Address 2
cdrh_510k_approvals	CITY	City
cdrh_510k_approvals	State_Country	State / Province
cdrh_510k_approvals	Country_Code	Country
cdrh_510k_approvals	Postal_Code	ZIP
cdrh_510k_approvals	Postal_Code_Non_US	Postal Code

5.2. Medical Device Listings

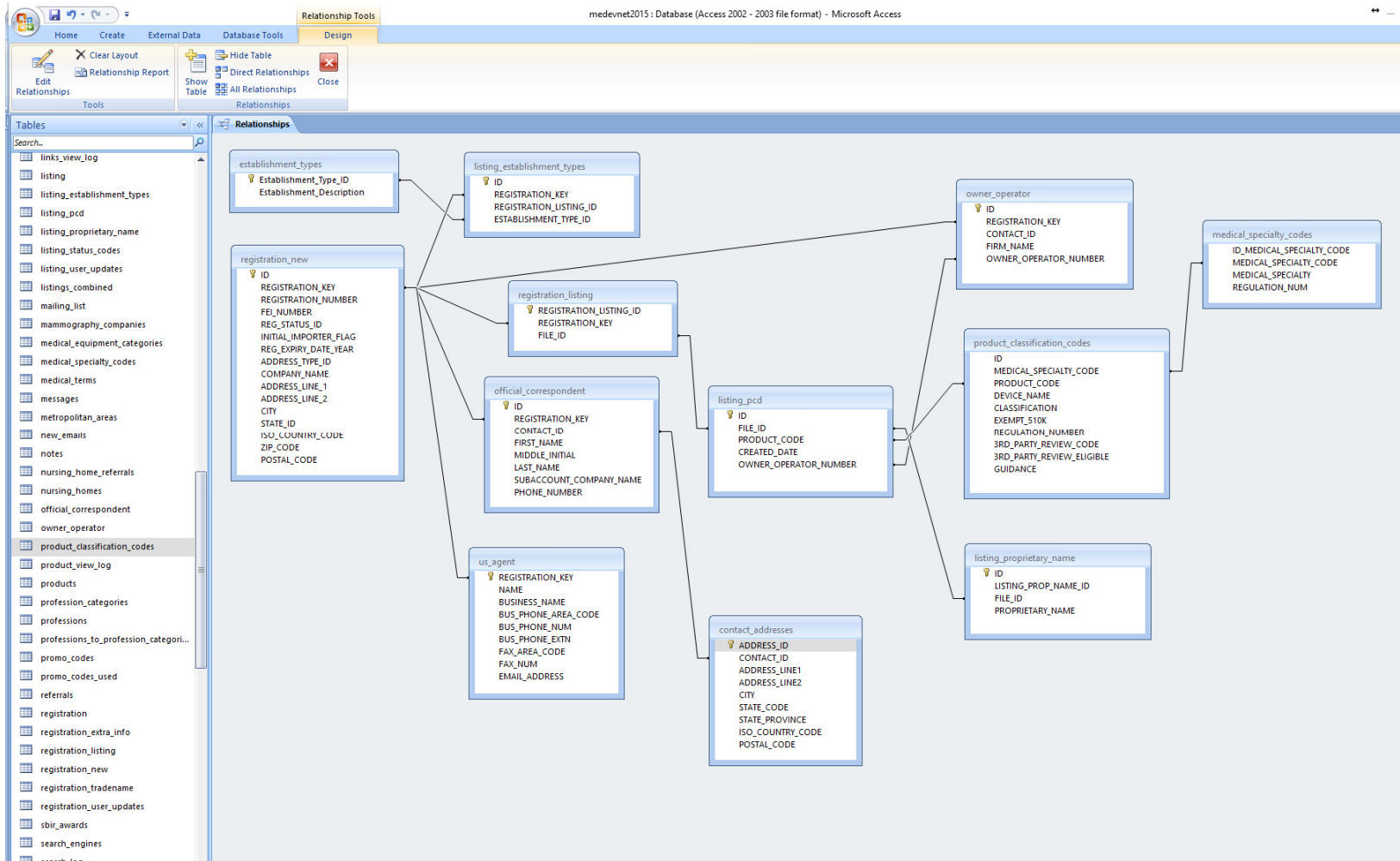| Table	Field	Export Column
product_classification_codes	CLASSIFICATION	Device Class
listing_pcd	PRODUCT_CODE	Product Code
listing_proprietary_name	PROPRIETARY_NAME	Proprietary Device Name
product_classification_codes	DEVICE_NAME	Common Device Name
registration_new	COMPANY_NAME	Company Name
registration_new	ADDRESS_LINE_1	Address 1
registration_new	ADDRESS_LINE_2	Address 2
registration_new	CITY	City
registration_new	STATE_ID	State / Province
registration_new	ISO_COUNTRY_CODE	Country
registration_new	ZIP_CODE	ZIP
registration_new	POSTAL_CODE	Postal Code
listing_pcd	created_date	Listing Created Date
product_classification_codes	EXEMPT_510K	510(k) Exempt
registration_new	REGISTRATION_NUMBER	Registration Number
registration_new	FEI_NUMBER	FEI Number
registration_new	REG_STATUS_ID	Status
registration_new	REG_EXPIRY_DATE_YEAR	Date of Registration Status
establishment_types	Establishment_Description	Establishment Type

6. Database Entity Relationship Diagrams
   6.1. 510ks

The 510ks database is a just one main data table with a lookup table for common device names joined via product code. See next page for medical device listings

Special Reporting Project for a Medical Device Manufacturer

6.2. Medical Device Listings

Special Reporting Project for a Medical Device Manufacturer

7. Web-Based Query Forms
   7.1. 510k Search Form:
      http://510kdecisions.com/search/index.cfm?fuseaction=advanced_search_form
      7.1.1.   Sample Query
      o   Product Code: GFD (12 records)
      o   Click export to download / view CSV.

Generated query:

```
select a.*,b.*
from 510kdecisions.cdrh_510k_approvals a, product_codes b
where a.product_code = b.product_code
and a.product_code = 'GFD'
```


   7.2. Medical Devices Search Form:
      http://medevnet.com/search/pcd/index.cfm?fuseaction=search_pcd_form
      7.2.1.   Sample Query
         •   Product Code: GFD, US State Code: CA (16 records)
         •   Click export to download / view CSV.

Generated queries:

Query 1: pcd_ids (*running this query separately to get a list of primary keys rather than joining the table listing_pcd in the next query significantly improves performance*)

```
select id
from listing_pcd
where listing_pcd.PRODUCT_CODE = 'GFD'
```

Query 2: results
```
SELECT
establishment_types.Establishment_Type_ID,
establishment_types.Establishment_Description,
listing_pcd.file_id,
listing_pcd.PRODUCT_CODE,
listing_pcd.created_date,
listing_pcd.OWNER_OPERATOR_NUMBER,
listing_proprietary_name.LISTING_PROP_NAME_ID,
listing_proprietary_name.PROPRIETARY_NAME,
medical_specialty_codes.MEDICAL_SPECIALTY_CODE,
medical_specialty_codes.MEDICAL_SPECIALTY,
medical_specialty_codes.REGULATION_NUM,
```

Special Reporting Project for a Medical Device Manufacturer

owner_operator.CONTACT_ID,
owner_operator.FIRM_NAME,
owner_operator.OWNER_OPERATOR_NUMBER,
product_classification_codes.DEVICE_NAME,
product_classification_codes.CLASSIFICATION,
product_classification_codes.EXEMPT_510K,
product_classification_codes.REGULATION_NUMBER,
registration_new.id,
registration_new.REGISTRATION_KEY,
registration_new.REGISTRATION_NUMBER,
registration_new.FEI_NUMBER,
registration_new.REG_STATUS_ID,
registration_new.INITIAL_IMPORTER_FLAG,
registration_new.REG_EXPIRY_DATE_YEAR,
registration_new.ADDRESS_TYPE_ID,
registration_new.COMPANY_NAME,
registration_new.ADDRESS_LINE_1,
registration_new.ADDRESS_LINE_2,
registration_new.CITY,
registration_new.STATE_ID,
registration_new.ISO_COUNTRY_CODE,
registration_new.ZIP_CODE,
registration_new.POSTAL_CODE

FROM
establishment_types,
listing_establishment_types,
listing_pcd,
listing_proprietary_name,
medical_specialty_codes,
owner_operator,
product_classification_codes,
registration_listing,
registration_new

WHERE registration_new.ADDRESS_TYPE_ID = 'F'

and medical_specialty_codes.medical_specialty_code =
product_classification_codes.medical_specialty_code

and establishment_types.establishment_type_id =
listing_establishment_types.establishment_type_id

and registration_listing.registration_listing_id =
listing_establishment_types.registration_listing_id

and registration_listing.registration_key = registration_new.registration_key

and registration_new.registration_key = OWNER_OPERATOR.registration_key

and registration_new.registration_key = listing_establishment_types.registration_key

and listing_pcd.file_id = registration_listing.file_id
and listing_pcd.file_id = listing_proprietary_name.file_id
and listing_pcd.product_code = product_classification_codes.product_code
and listing_pcd.OWNER_OPERATOR_NUMBER =
owner_operator.OWNER_OPERATOR_NUMBER

and listing_pcd.id in
(47833,175746,26052,147787,102866,153178,46705,65679,1128,30784,69636,50621,127723,85150,77579,171188,20703,109709,83971,171759,153458,72368,22217,154373,26042,122911,149927,118478,189596,118962,85361,52743,112542,19593,88518,54379,69318,22255,175035,70842,197870,97916,69641,124249,120629,162112,6142,157,102932,102046,183714)

AND registration_new.STATE_ID = 'CA'